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In the Application of:
Geoffrey Flagstad

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BRIEF ON APPEAL

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I. INTRODUCTION

A patient needs a way to store his or her medical records, maintained by past and present medical professionals, so that the records pertinent at a particular moment may be quickly transferred to a medical professional who is treating the patient, without compromising strict confidentiality. The presently claimed invention addresses those needs, while the prior art of record does not.

A fully developed and organized medical history of a patient is one of the most valuable tools that a medical professional uses when diagnosing and treating a patient. Indeed, one of the first things a medical professional typically does is interview the patient to obtain a medical history including information such as current medications, allergies, past test results, etc. Because of the need for a medical professional to have a medical history available, medical professionals have invested considerable effort into compiling, storing, and retrieving their own medical records pertaining to their own patients. But past records compiled by one medical professional are not so easily retrieved by another medical professional.

The Health Insurance Portability and Accountability Act (HIPAA), addressing the need for a patient's records held by a medical professional to remain confidential, directs that no one, including another medical professional, is able to obtain records from a medical professional without written permission from the patient. Many times written permission is not obtainable when the medical records are most urgently needed, for instance when a patient is unconscious, no family member is available, and the patient needs emergency medical treatment. HIPAA thus inhibits the availability of certain information that is crucial to efficient and effective medical treatment.

By establishing strict procedural guidelines and severe sanctions for noncompliance, HIPAA erects further barriers to the quick access of one medical professional's records by

another medical professional that needs the records for emergency care. Medical professionals who store medical records are often afraid to share them, lest they run afoul of HIPAA requirements. Other medical professionals, without being able to obtain medical records, often perform redundant tests or find it necessary to do without third-party information that could potentially save the patient's life.

The present invention addresses this dilemma between the needs for privacy and access by providing a solution that is compatible with HIPAA to get medical records maintained by other medical professionals to a medical professional who needs them urgently.

II. REAL PARTY IN INTEREST

The real party in interest of this pending patent application is MedLifeCard, Inc. MedLifeCard, Inc. is the owner by assignment of all rights to patent application 10/679,749.

III. RELATED APPEALS AND INTERFERENCES

Not Applicable

IV. STATUS OF CLAIMS

Claims 1-2 and 5-64 are rejected and currently appealed. Claims 3 and 4 have been canceled.

More particularly, claims 1-2 and 5-64 are rejected under 35 U.S.C. § 101 because the claimed invention is stated to be directed to non-statutory subject matter.

Claims 1-2, 5-8, 11-32, and 35-64 are rejected under 35 U.S.C. § 103(a), as they are stated to be unpatentable over Segal (US 2001/0041991), in view of Joao (6,283,761), and in view of Official Notice.

Claims 33 and 34 are rejected under 35 U.S.C. § 103(a), as they are stated to be unpatentable over Segal, Joao, and Official Notice as applied to claim 30, and further in view of Judson et al. (US 2005/0026117).

Claims 9 and 10 are rejected under 35 U.S.C. § 103(a), as they are stated to be unpatentable over Segal, Joao, and Official Notice as applied to claims 1 and 30, and further in view of Mok et al. (US 2003/0140044).

V. STATUS OF AMENDMENTS

Not Applicable

VI. SUMMARY OF CLAIMED SUBJECT MATTER

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) creates national standards to protect the privacy of personal health information. HIPAA was intended to prevent the reckless dissemination of personal health information.[1] However, HIPAA's requirement of procedural accountability has also been problematic because it combines strict procedural behavior with severe sanctions for noncompliance.[2] As a result, service providers, uncertain about their responsibilities, often respond with an overly guarded approach to disclosing information.[3] The result of strict procedural requirements and uncertainty surrounding those requirements is that it is often difficult for a medical professional to quickly access a patient's medical history maintained by another medical professional.[4]

Taking into account that 40% of all hospital admissions start in the emergency room, where the review of a patient's health information must be performed under narrow time constraints, HIPAA requirements often place both patients and doctors in a precarious situation.[5] Consider the patient who is admitted to the emergency room unconscious and thus cannot give the emergency room physician important health information. As a result of HIPAA requirements, the emergency room medical professional may not be able to obtain the patient's medical history from another medical professional as quickly as necessary.[6] The medical professional may thus be forced either to perform costly and unnecessary testing or to provide treatment while lacking critical information.[7]

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[1] Specification, page 3, paragraph 0007
[2] Id.
[3] Specification, page 3, paragraph 0008
[4] Id.
[5] Specification, page 2, paragraph 0004
[6] Specification, page 1, paragraph 0004
[7] Specification, page 1, paragraph 0002

The present invention seeks to allow for quick disclosure of the patient's medical history to a third party without restriction or delay by HIPAA.[8] Because HIPAA regulates the medical professionals or facilities maintaining medical records, as well as any entity other than the patient that performs data processing on the medical records (these regulated parties are known as "covered entities"), the service provider of the presently claimed invention must refrain from data processing of the records to avoid being classed as a "covered entity" and restricted by HIPAA.[9] Yet data processing such records (organizing them, summarizing them, etc.) is a necessary and routine step for making relevant information more easily accessible so that the portion of the record relating to a current emergency can be quickly identified and used to treat the patient.[10] An emergency room medical professional does not have the time to sift through thousands of pages of records from a lifetime of medical care to find the particular nuggets, such as a record of an allergy to a particular medication, that might expedite the patient treatment or even save the patient's life. In the cited prior art, a service provider processes at least some of the data, so its disclosure is subject to HIPAA restrictions.[11]

The present invention addresses this problem uniquely by recognizing that the necessary data processing can and must be done by the only person who can legally process a patient's medical record without HIPAA restrictions – the patient himself or herself.[12] The service provider facilitates this process, which many patients cannot do unaided, by providing a format for storing the information, showing the patient how to acquire the medical records and organize and process them into a more useful form, listing what information should be included in a summary record, the specific notations in a medical record that identify such information, and so

[8] Specification, page 10, paragraph 0033
[9] Specification, page 11, paragraph 0035
[10] Specification, page 8, paragraph 0024
[11] Specification page 11, paragraph 0035
[12] Specification, page 12, paragraph 0038

forth.[13] The service provider then is able to store and communicate the already-processed records provided by the patient, as directed by the patient in advance, without engaging in data processing and thus encountering the restrictions provided by HIPAA.[14]

Independent Claims 1, 19, and 30 are illustrative of the invention and read:

> 1. A method for a service provider (pages 5-6, paragraph 0015, lines 1-4; page 10, paragraph 0032, lines 2-6) to obtain a medical record of a patient from a covered entity (Figure 1, reference character 70) in a form (Figure 2, reference character 220; Figure 3, reference character 100) allowing said service provider to quickly disclose said medical record without restriction by the Health Insurance Portability and Accountability Act of 1996 (page 5, paragraph 0014, lines 1-4; page 8, paragraph 0025, lines 1-3), the method comprising the following steps carried out by a service provider (pages 5-6, paragraph 0015, lines 1-4; page 10, paragraph 0032, lines 2-6) that is not the patient (page 10, paragraph 0032, lines 1-2) or a covered entity (page 2, paragraph 0006, lines 9-10; page 5, paragraph 0014, line 2; page 10, paragraph 0034, lines 1-15; Figure 1, reference character 70):
>
> A. inducing said patient to receive said medical record from a covered entity (page 5, paragraph 0015, lines 1-2; Figure 1, reference character 70);
>
> B. receiving said medical record from said patient in a storage format (page 6, paragraph 0016, lines 2-10) without data processing said medical record (page 7, paragraph 0020, lines 1-11);

[13] Id.
[14] Specification, page 7, paragraph 0021

C. storing said medical record in a memory (Figure 1, reference characters 44 and 50) in a form (Figure 2, reference character 220; Figure 3, reference character 100) from which said medical record can be reproduced in said storage format (page 7, paragraph 0020, lines 1-3; Figure 2, reference character 220; Figure 3, reference character 100), without data processing said medical record (page 7, paragraph 0020, lines 7-11);

D. obtaining agreement in advance with the patient that the service provider shall transmit said medical record to a third party under defined conditions (page 7, paragraph 0021, lines 1-3); and

E. transmitting said medical record to a third party when the defined conditions occur (page 7, paragraph 0021, lines 3-12), without data processing said medical record (page 7, paragraph 0020, lines 7-11).

19. A method to induce conversion of a medical record of a patient from a covered entity (Figure 1, reference character 70) to a form (page 7, paragraph 0018, lines 1-3; Figure 2, reference character 220; Figure 3, reference character 100) allowing quick disclosure of said medical record to a third party without restriction by the Health Insurance Portability and Accountability Act of 1996 (page 5, paragraph 0014, lines 1-4; page 10, paragraph 0033, lines 1-3), the method comprising:

A. a service provider that is not the patient or a covered entity (page 10, paragraph 0032, lines 1-2; page 10-11, paragraph 0034, lines 1-18;

Figure 1, reference character 70), inducing said patient to obtain possession of said medical record from a covered entity (page 5, paragraph 0015, lines 1-2; Figure 1, reference character 70);

B. said service provider inducing said patient (page 10, paragraph 0032, lines 1-2) to convert said medical record into a storage format (page 7, paragraph 0018, lines 2-3; Figure 2, reference character 220; Figure 3, reference character 100); and

C. said service provider inducing said patient to store said medical record in a memory (Figure 1, reference characters 44 and 50) in said storage format (page 7, paragraph 0020, lines 1-3; Figure 2, reference character 220; Figure 3, reference character 100) without data processing said medical record by the service provider (page 7, paragraph 0020, lines 1-11).

30. A medical and personal information system for obtaining and storing a medical record of a patient from a covered entity in a form (Figure 2, reference character 220; Figure 3, reference character 100) allowing quick disclosure of said medical record to a third party without restriction by the Health Insurance Portability and Accountability Act of 1996 (pages 8-9, paragraph 0025, lines 1-4), the system comprising:

A. a communication interface (pages 8-9, paragraph 0025, lines 4-7; Figure 1, reference character 210) provided at least in part by a service provider (pages 5-6, paragraph 0015, lines 1-4; page 10, paragraph 0032,

lines 2-6) that is not the patient (pages 5-6, paragraph 0015, lines 1-12) or a covered entity (page 10, paragraph 0034, lines 1-15; Figure 1, reference character 70), said interface (Figure 1, reference character 210) being adapted for inducing said patient to obtain possession of said medical record of said patient from a covered entity (page 9, paragraph 0015, lines 1-10; Figure 1, reference character 70); and

B. a data storage device (pages 8-9, paragraph 0025, lines 7-9; Figure 1, reference characters 45 and 46) provided at least in part by a service provider that is not the patient or a covered entity; page 8, paragraph 0022, lines 1-6; Figure 1, reference character 70), said storage device comprising a memory (page 8, paragraph 0022, lines 1-6; Figure 1, reference characters 44 and 50) adapted for storing said medical record in a form (Figure 2, reference character 220; Figure 3, reference character 100) from which it can be reproduced in a storage format (page 7, paragraph 0020, lines 1-3; Figure 2, reference character 220; Figure 3, reference character 100), wherein said storage device is configured to store said medical record without data processing said medical record (page 7, paragraph 0020, lines 1-11).

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The principal grounds of rejection on appeal are:

(1) Whether claims 1-2 and 5-64 (all pending claims) are unpatentable under 35 U.S.C. § 101.

(2) Whether claims 1-2, 5-8, 11-32, and 35-64 are unpatentable under 35 U.S.C. § 103(a) over Segal et al., in view of Joao, and further in view of Official Notice.

(3) Whether claims 33 and 34 are unpatentable under 35 U.S.C. 103(a) over Segal et al., Joao, and Official Notice, as applied to claim 30 and further in view of Judson et al.

(4) Whether claims 9 and 10 are unpatentable under 35 U.S.C. § 103(a) over Segal et al., Joao, and Official Notice, as applied to claim 1 and further in view of Mok et al.

VIII. ARGUMENT

A. Claims 1-2 and 5-64 are patentable under 35 U.S.C. § 101

The 35 U.S.C. § 101 rejection as made in the Office action of November 28, 2007, states,

> Claims 1-2 and 5-64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. More specifically, claims 1-2 and 5-64 are directed to non-statutory subject matter because these claims subvert existing federal statutes, such as the Health Insurance Portability And Accountability Act Of 1996 (HIPAA), through the use of the patent system and therefore, are against public policy.

This is not a proper legal ground of rejection, nor is there a factual basis for the assertions that the rejected claims are "directed to non-statutory subject matter," "subvert existing federal statutes" or are "against public policy." This rejection therefore must be reversed as to all claims.

1. Claims 1-2 and 5-64 are directed to statutory subject matter

35 U.S.C. § 101 states,

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 100(b) clarifies this statute, stating, "The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

35 U.S.C. § 101 is available to reject a claim reciting an invention that is not within one of the classes of statutory subject matter recited in that section of the statute. MPEP § 706.03 (a)(I). But such rejections should be rare. As the Supreme Court has recognized, Congress chose the expansive language of 35 U.S.C. § 101 so as to include "anything under the sun that is made by man" as statutory subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980) ; MPEP § 2106(IV)(A). In *Chakrabarty* the Supreme Court further stated:

> In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope. The relevant legislative history also supports a broad construction. * * * The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man."

Id; see also, In re Alappat, 33 F.3d 1526, 1542, 31 USPQ2d 1545, 1556 (Fed. Cir. 1994) *(en banc)*. "The subject matter courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena." MPEP § 2106(IV)(A). On the other hand, a practical application of an abstract idea, law of nature or natural phenomenon is patentable subject matter. *See, Diamond v. Diehr*, 450 U.S. 175, 187, 209 USPQ 1, 8 (1981) ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.")

The present claims 1-29, 50-59, and 64 all expressly recite methods. A "method" is one of the categories of inventions expressly recognized as patentable subject matter under 35 U.S.C. § 101. For example, claim 1 recites a series of acts or steps to be performed: "A. inducing said patient to receive said medical record from a covered entity; B. receiving said medical record from said patient ...; C. storing said medical record in a memory ...; D. obtaining agreement in advance with the patient ...; and E. transmitting said medical record to a third party...."

Even if the medical record is entirely electronic (and today it often is not, particularly as received from a health care professional or entity), it is necessarily stored (step C) in the physical form of a memory device that has been physically modified, as by changing the magnetic state of physical elements of a magnetic memory, changing the charges of physical elements of a silicon memory, or engraving a pattern of grooves in a CD-ROM.

The presently claimed method plainly has not been shown by the Examiner to be an abstract idea, law of nature or natural phenomenon. "The examiner bears the initial burden ... of presenting a prima facie case of unpatentability," *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992), and has not done so here. Thus, none of the established exceptions to statutory subject matter applies to the present method claims, nor is the invention anything less than a practical application of a concrete idea.

The remaining claims, present claims 30-49 and 60-63, recite systems of hardware components that cooperate with each other to form a machine. For example, the elements of claim 30 are "A. a communication interface..." and "B. a data storage device...." These components are adapted to work together to obtain and store medical records. A "machine" is one of the categories of inventions expressly recognized as patentable subject matter under the statute. The presently claimed machine is a physical object, and plainly has not been shown to be an abstract idea, law of nature or natural phenomenon, thus none of the established exceptions to statutory subject matter applies.

The Office has not established any reason to suppose that the present claims, directed to machines and methods, define non-statutory subject matter. Thus, no *prima facie* case of unpatentability has been made out under 35 U.S.C. § 101. The present rejection must be withdrawn.

2. A rejection based on the assertion that the invention is "against public policy" has no proper legal basis.

Second, 35 U.S.C. § 101 is sometimes used to reject a claim to an invention that is not "useful," i.e., lacks utility. MPEP § 706.03 (a)(II). But "against public policy" is no longer a proper basis for rejecting a claim under 35 U.S.C. § 101 for lack of utility.

> A rejection under 35 U.S.C. 101 for lack of utility should not be based on grounds that the invention is frivolous, fraudulent or against public policy. *See Juicy Whip Inc. v. Orange Bang Inc.*, 185 F.3d 1364, 1367-68, 51 USPQ2d 1700, 1702-03 (Fed. Cir. 1999). ("[Y]ears ago courts invalidated patents on gambling devices on the ground that they were immoral..., but that is no longer the law...Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted...we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public."). The statutory basis for this rejection is 35 U.S.C. 101.

MPEP § 706.03(a) (II) (ellipses in original; emphasis added). The MPEP thus expressly recognizes that the role of the US Patent and Trademark Office is limited to determining patentability of inventions, rather than addressing other issues such as whether the invention promotes the public welfare – issues that are the job of other government agencies.

This case is analogous to *Juicy Whip, Inc., v. Orange Bang, Inc.*, 185 F.3d 1364, 51 USPQ2d 1700 (Fed. Cir. 1999) (reversing district court finding of invalidity under 35 U.S.C. § 101 based on lack of utility for "deceptiveness"), which stated:

> Of course, Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness. Cf. 42 U.S.C. § 2181(a) (exempting from patent protection inventions useful solely in connection with special nuclear material or atomic weapons). Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.

Juicy Whip, Inc., v. Orange Bang, Inc., 185 F.3d 1364, 1368, 51 USPQ2d 1700, 1703 (Fed. Cir. August 6, 1999). *See also, In re Watson*, 517 F.2d 465, 474-76, 186 USPQ 11, 19 (CCPA 1975) (stating that it is not the province of the USPTO to determine, under section 101, whether drugs are safe). The USPTO has a big enough job as it is in administering the patent laws.

3. The present invention is for, not against, public policy and does not "subvert" a federal statute

The Examiner has not pointed out any factual basis for maintaining that the present invention "subverts" the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA). Again, for lack of a *prima facie* case, the rejection must be reversed. Additionally, the Examiner will be unable to make out a *prima facie* case because the present invention does not in any way "subvert" any statute; it promotes important medical and governmental policies, such as the following:

> As the nation embarks on the widespread deployment of EHRs [electronic health records], a variety of concomitant challenges and barriers must be addressed. One of these is interoperability, or the ability to exchange patient health information among disparate clinicians and other authorized entities in real time and under stringent security, privacy and other protections. Interoperability is an essential factor in using health information technology to improve the quality and efficiency of care in the United States. Interoperability is necessary for compiling the complete experience of a patient's care, for maintaining a patient's personal health records and for ensuring that complete health information is accessible to clinicians as the patient moves through various healthcare settings.

> Interoperability is needed for clinicians to make fact-based decisions so medical errors and redundant tests can be reduced.

FEDERAL REGISTER, Vol. 69, No. 219 (November 15, 2004), pp. 65599-65601, at pp. 65599-65600. The present invention furthers this policy by providing medical records that have been organized and stored in a manner to increase their value to a reviewing physician, and permitting access to those records by medical health professionals only under conditions agreed upon by the patient, thus preserving the patient's confidentiality while providing access to those authorized in advance by the patient. This public purpose becomes particularly vital when the patient chooses, in advance of need, to give an emergency medical provider access to his or her medical records in the event of a medical condition that prevents him or her from giving permission on the spot. When such an emergency occurs, the present invention allows the patient's choice to be carried out.

4. The present rejection under 35 U.S.C. § 101 has no legal or factual basis, and so must be reversed

In sum, the rejection under 35 U.S.C. § 101 has no proper basis. The subject matter of each claim is within one of the statutory classes specified by 35 U.S.C. § 101, and is not directed to an excluded abstract idea, law of nature or natural phenomenon. MPEP § 2106(IV)(A). Public policy grounds are not an appropriate basis for a rejection under 35 U.S.C. § 101. Moreover, the present invention promotes, and does not "subvert," public policy goals such as those of HIPAA. The present invention furthers the important public policy of allowing access to a patient's electronic medical records in an emergency, while preserving the patient's right to keep the information confidential. Therefore, the rejection should be withdrawn.

B. Claims 1-2, 5-8, 11-32, and 35-64 are patentable under 35 U.S.C. § 103(a) over Segal, in view of Joao, and further in view of Official Notice.

1. Taken together, the references applied in the rejections based on the combination of the teachings of Segal and Joao under 35 U.S.C. § 103(a) fail to disclose a service provider storing a medical record *without data processing* said medical record.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970); *See also* § 2143.03 MANUAL OF PATENT EXAMINING PROCEDURE (8th ed., rev. 5, 2006) ["MPEP"]..

Neither Segal nor Joao teaches the presently claimed limitation requiring a service provider who is not a covered entity under HIPAA to refrain from data processing a medical record, and only store and transmit the medical record as presented by the patient. The November 28, 2007, Office action recognizes that Segal fails to disclose a method carried out by a service provider that is not the patient or a covered entity comprising:

(1) storing said medical record *without data processing* said medical record
(2) obtaining agreement in advance with the patient that the service provider shall transmit said medical record to a third party under defined conditions; and
(3) transmitting said medical record to a third party when the defined conditions occur, *without data processing* said medical record.[15]

[15] Office action of Nov. 28, 2007, pages 4-5.

The November 28, 2007, Office action thus relies upon Joao for the teaching that the service provider should store the medical record *without data processing said medical record.* However, Joao neither teaches nor suggests this claim limitation.

a. Nowhere in any of the embodiments of the invention disclosed in Joao is there a teaching or suggestion of storing a medical record *without data processing said medical record.*

Joao discloses numerous distinct embodiments, each of which involves some form of data processing. The first embodiment teaches a process of performing a diagnosis of a sickness or condition and is illustrated by Figures 7A and 7B. The central processing computer will, at step 705, "receive and process" the patient symptoms and will "perform a comprehensive diagnostic evaluation".[16] Processing a medical record is thus necessary in this process. The next embodiment teaches a process of evaluating or monitoring treatments and is illustrated by Figures 8A and 8B. In step 803, a "processing routine" using the stored records is required.[17]

Another embodiment teaches the creation of a comprehensive patient healthcare database that can be accessed by any medical professional or other party to access the patient's healthcare information. This process, illustrated by Figures 9A and 9B, requires that after a patient enters his medical information, the central processing computer will "process and store" that information[18]. This embodiment explicitly teaches the processing of the medical records by the service provider. The service provider performing the invention of Joao is therefore inherently a covered entity under HIPAA. Joao thus explicitly teaches away from the presently claimed invention.

[16] Evidence Appendix, Joao, at col. 25, lines 30-38.
[17] Evidence Appendix, Joao, at col. 28, lines 37-42.
[18] Evidence Appendix, Joao, at col. 29, lines 49-55.

Further embodiments of Joao describe processes where data processing is a required step. The embodiment illustrated by Figure 10 teaches a method of locating medical professionals or payers, wherein the data entered by the patient is processed to identify a healthcare professional or insurance company.[19] The embodiment illustrated by Figure 11 teaches a method of accessing a medical professional's schedule to create an appointment. The schedule is then updated, or processed, by the central processing computer.[20] The embodiment illustrated by Figures 12A and 12B teaches a method of providing notification in response to an event or occurrence. Upon receiving information of an occurrence, the central processing computer processes the information to generate a notification message.[21] The embodiment illustrated by Figures 13A, 13B, and 13C teaches a method of processing healthcare claims[22], while the embodiment illustrated by Figures 14A and 14B teaches a combined process of performing a diagnosis and submitting a claim in response to the diagnosis.[23] In the final embodiment, illustrated by Figures 15A and 15B, a vast amount of healthcare information is stored and processed to create a simulator for training.[24]

None of the embodiments disclosed by Joao teach a method of storing a medical record *without data processing said medical record.*

b. The passages of Joao relied upon in the November 28, 2007, Office action neither teach nor suggest storing a medical record *without data processing said medical record.*

The November 28, 2007, Office action relies on a general section of Joao that merely sets forth the basic utility of the invention:

[19] Evidence Appendix, Joao, at col. 30, lines 63-67.
[20] Evidence Appendix, Joao, at col. 32, lines 65-67.
[21] Evidence Appendix, Joao, at col. 34, lines 35-42.
[22] Evidence Appendix, Joao, at col. 35, lines 11-12.
[23] Evidence Appendix, Joao, at col. 36, lines 23-29.
[24] Evidence Appendix, Joao, at col. 38, lines 42-51.

> The present invention provides an apparatus and methods for providing healthcare information and/or healthcare-related information which overcomes the shortcomings of the prior art.[25]

The November 28, 2007, Office action incorrectly implies that because "data processing" is not mentioned in this section, it teaches a method of providing healthcare information without data processing. Joao does not disclose a limitation that the method for providing healthcare information is taught to be performed without data processing merely because the specific term "data processing" was not immediately present in a particular sentence. Such a broad statement cannot be understood to teach one of ordinary skill either the steps taken in, or those excluded from, a method for providing healthcare information. There is nothing in this general statement to suggest a method of providing healthcare information without data processing. This section of Joao would not have led one of ordinary skill to provide healthcare information without data processing. Rather, the November 28, 2007, Office action relies upon knowledge gleaned from the Applicant's disclosure to find such a suggestion. This is improper hindsight reasoning.[26]

The November 28, 2007, Office action further relies on the use of alternative language, such as "can" and "and/or" in the following passages of Joao:

> The apparatus also includes an intermediary communication device or computer which is associated with an intermediary, a broker, an agent, and/or any other individual and/or entity, that can utilize the present invention **in order to act for and/or on behalf of any other individual, party, or entity, described herein.** The intermediary computer(s) **can** communicate with, and operate in conjunction with, central processing computer and/or any of the other computers and/or computer systems described herein.[27]

> Each of the central processing computer(s), the provider computer(s), the payer computer(s), the patient computer(s), and/or the intermediary computer(s), **can** transmit information to, as well as receive information from, any of the computers described herein. In this regard, each of the computers **can** communicate with, process information from, **and/or** share data and/or information with, each other

[25] Evidence Appendix, Joao, at col. 2, lines 26-30.
[26] *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971); see also MPEP § 2145.
[27] Evidence Appendix, Joao, at col. 3, lines 26-33.

> and/or any other computer or computers described herein and/or utilized in conjunction with the present invention. In this manner, data and/or **information transfer between any of the computers can take place in a bi-directional manner**.[28]

Nowhere in these passages is there a teaching, or a suggestion, that the apparatus is intended to store a medical record without data processing. The mere teaching that the computers in a network can be used for data processing does not suggest a method of providing healthcare information without data processing. These sections of Joao would not have led one of ordinary skill to provide healthcare information without data processing. This again is improper hindsight reasoning.[29]

The November 28, 2007, Office action also concludes that storing a medical record without data processing said medical record is implied by a "broad, yet reasonable" interpretation of the following section of Joao:

> The apparatus and method of the present invention can be utilized in numerous preferred embodiments in order to provide a vast array of healthcare and healthcare-related services for any one or more of the various parties described herein. Any patient, user, provider, payer, and/or intermediary, may utilize the present invention in the same, similar, and/or analogous manner.[30]

There is nothing in this general statement to suggest a method of providing healthcare information without data processing. This section of Joao would not have led one of ordinary skill to provide healthcare information without data processing; rather the November 28, 2007, Office action relies upon knowledge gleaned from the Applicant's disclosure to find such a suggestion. This is another example of improper hindsight reasoning.[31]

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[28] Evidence Appendix, Joao, at col. 3, lines 34-45.
[29] *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971); MPEP § 2145
[30] Evidence Appendix, Joao, at col. 4, lines 27-33.
[31] *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971); MPEP § 2145

c. Rebuttal of additional arguments

The applicant will now address the new arguments made on pages 15-17 of the November 28, 2007, Office action.

In the paragraph on page 16 of the Office action starting with "First, ..." the argument is presented that the claims are met by Segal because, "until the service provider actually downloads the patient's medical record and modifies it, NO 'data processing' has occurred (Segal: pg. 12, ¶ [0151])." In other words, the suggestion is made that there could be a period of time after the service provider receives a record from the patient and before the service provider engages in data processing, so steps A and B of the present claim 1 might be argued to be met.

But claim 1 also requires two other steps to be performed by the service provider, without data processing: "C. storing said medical record in a memory in a form from which said medical record can be reproduced in said storage format, without data processing said medical record;" and "E. transmitting said medical record to a third party when the defined conditions occur, without data processing said medical record." Segal, pg. 12, ¶ [0151], does not indicate that the service provider should perform these functions.

For one example, assume the patient brings in an update, and a program operated by the service provider selects what files of the provided update to store, or what file(s) to store the update in, based on the content of the data (determined, for example, by word searching the data for keywords indicating the diagnosis). This would be routine practice. The service provider is processing data by word searching it, and thus is not "storing ... without data processing," as required by step C of claim 1.

For another example, Segal, pg. 12, ¶ [0151], does not describe a service provider who is not a covered entity transmitting the data to a third party, as required by step E of claim 1. This paragraph of Segal only discloses, as transmission of the data to a third party, the patient taking the data directly to her physician. The physician is a covered entity, thus neither the patient nor the physician is "a service provider that is not the patient or a covered entity" as required by claim 1. In other words, the service provider is not transmitting the data to the third party, so step E is not met.

Moreover, Segal, pg. 12, ¶ [0151], does not state or suggest that the service provider should refrain from data processing at any point. Instead, the reference is used to provide

snippets of activity during which data processing has not yet occurred, rather than showing any prior art suggesting that the information should be solicited from the patient, stored, then retrieved and transmitted to a third party as recited in the present claims, all without data processing at any point prohibited by the claimed invention.

To conclude this point, the new Segal arguments in the Office action address step B of claim 1 in isolation – "receiving said medical record from said patient in a storage format, without data processing said medical record." The applicant agrees that step B would be performed if the patient scanned her own medical record to make a PDF file, stored the PDF record on a CD, and handed the CD to the service provider, then the service provider merely possessed the CD. But claim 1 also recites steps C and E, respectively requiring the service provider to store the record in a memory and transmit it to a third party, both also without data processing. The arguments relying on Segal in the Office action do not address these steps or explain why they would be obvious in view of the prior art.

In the paragraph on page 16 of the Office action starting with "Second, ..." the argument is presented that storing a medical record without data processing is met by Joao, from col. 39, line 53, to col. 40, line 12, and in col. 4, lines 26-33. The Office action sums up the argument as follows: "In other words, a service provider may possess the non-data-processed portable medical record in the same manner as the patient."

The portions of the Joao reference relied on by the Office action provide no disclosure of the claimed invention, and do not support the assertions in the Office action. The passage of Joao from col. 39, line 53, to col. 40, line 12, has nothing to do with receiving, storing, or transmitting a medical record, as presently claimed. It has to do with storing and reading authorization information, as on an identification card, to determine if the holder of the card shall have access to a database containing the medical information. Similarly, the passage of Joao in col. 4, lines 26-32, also discloses nothing about the present invention. The cited parts of Joao are thus irrelevant.

2. The combination of references is inappropriate because Segal explicitly teaches a step of data processing and is not properly combined with a reference that teaches a lack of data processing.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); MPEP § 2141.02. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); MPEP § 2143.01.

The November 28, 2007, Office action stated that it would have been obvious at the time of invention to combine the teachings of Joao and the teachings of Segal with the motivation of providing healthcare information to pertinent parties. However, Segal, considered in its entirety, necessarily describes the service provider engaging in data processing.[32] Combining the Segal reference that specifically teaches and requires data processing with any reference that is asserted to specifically teach refraining from data processing is improper. The combination is inappropriate because the proposed modification to the Segal process would change the principle of operation of the process itself, which prevents such a combination from rendering the claim *prima facie* obvious. Additionally, the combination of a reference that requires data processing with a reference that excludes data processing is an improper use of hindsight reasoning, based solely upon knowledge gleaned from the Applicant's disclosure.

[32] Evidence Appendix, Segal, at page 8, paragraph 0103; Segal, at pages 11-12, paragraph 0143

3. It was inappropriate to rely on Official Notice that transmitting medical records without data processing was old and well-known in the art, without any prior art of record cited as having taught this limitation.

The November 28, 2007, Office action recognizes that *Segal fails to disclose* a method carried out by a service provider that is not the patient or a covered entity comprising:

(4) storing said medical record *without data processing* said medical record

(5) obtaining agreement in advance with the patient that the service provider shall transmit said medical record to a third party under defined conditions; and

(6) transmitting said medical record to a third party when the defined conditions occur, *without data processing* said medical record.

The November 28, 2007, Office action thus relies upon Official Notice for the teaching that the service provider transmits medical records to a third party without data processing the medical records. This, however, is an improper use of Official Notice.

a. The use of Official Notice in the November 28, 2007, Office action is inappropriate because the step of transmitting medical records *without data processing* is not a fact that could be instantly and unquestionably demonstrated as well known.

Official Notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well-known, or to be common knowledge in the art, are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the Examiner must be "capable of such instant and unquestionable demonstration as to defy dispute." *See also In re Beasley*, 117 Fed. Appx. 739, 744 (Fed. Cir. 2004) (non-precedential),[33] MPEP § 2144.03.

[33] Non-Precedential Authority Appendix; http://www.fedcir.gov/contents.html (Noting that the former Federal Circuit rule against citation of non-precedential decisions has been superseded).

The limitation that the medical records must be transmitted *without data processing* is not a fact that is capable of instant and unquestionable demonstration as being well-known. Rather, the November 28, 2007, Office action apparently claims Official Notice because the prior art of record does not include such a teaching. Given that the prior art used in the rejection teaches data processing medical records, it can hardly be deemed unquestionable for one in the art to transmit medical records without data processing.

b. The use of Official Notice in the November 28, 2007, Office action is inappropriate because it was used as the principal evidence upon which the rejection was based.

Any facts to be established by Official Notice should be of notorious character and serve only to "fill in the gaps" in an insubstantial manner which might exist in the evidentiary showing made by the Examiner to support a particular ground for rejection. *Ahlert*, 424 F.2d at 1091, 165 USPQ at 421. It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence upon which a rejection was based. *In re Zurko*, 258 F.3d 1379, 1386, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001); *Ahlert*, 424 F.2d at 1092, 165 USPQ at 421; MPEP § 2144.03.

The use of Official Notice to teach the claim limitation of transmitting medical records to a third party without data processing the medical records is inappropriate. As previously noted, the Applicant's invention specifies that the service provider does not data process the medical records with which it deals and thus is not a covered entity of HIPAA. Accordingly, it is inappropriate to base the rejection of such a limitation on an unsupported statement that doing so is well known in the art. This is especially the case where the other prior art used in the rejection specifically teaches the use of data processing. The November 28, 2007, Office action uses Official Notice not to fill the gaps to support a particular rejection but rather as a primary basis

for the rejection itself, contradicting a teaching in the Segal reference of record. This is inappropriate and prohibited by *Zurko* and *Ahlert*.

c. The use of Official Notice in the November 28, 2007, Office action is inappropriate because it does not include any support or reasoning for its conclusion respecting the "without data processing" limitations.

If Official Notice is taken, the basis for such reasoning must be set forth explicitly. The Examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. *See In re Soli*, 317 F.2d 941, 945-46, 137 USPQ 797, 800 (CCPA 1963); *In re Chevenard*, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943); MPEP § 2144.03.

The November 28, 2007, Office action explains that Official Notice is taken with respect to the limitations of "obtaining agreement in advance with the patient that the service provider shall transmit said medical record to a third party under defined conditions and transmitting said medical record to a third party when the defined conditions occur."[34] However, there is no explanation why Official Notice may properly be taken with respect to the limitation of transmitting said medical record *without data processing* the medical record.[35] The use of Official Notice with respect to this limitation therefore is inappropriate absent persuasive reasoning in support of such a conclusion.

4. It was error to treat certain matters taken on Official Notice as admitted prior art when the Applicant adequately traversed the use of Official Notice.

To adequately traverse a finding based on Official Notice, Office policy is that an Applicant must specifically point out the supposed errors in the Examiner's action, which would

[34] Office action of Nov. 28, 2007 p. 5
[35] Office action of Nov. 28, 2007 p. 5

include stating why the noticed fact is not considered to be common knowledge or well-known in the art. *See* 37 CFR 1.111(b); *see also Chevenard,* 139 F.2d at 713, 60 USPQ at 241. If the Applicant adequately traverses the Examiner's assertion of Official Notice, the Examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. MPEP § 2144.03.

The Examiner contends that the Applicant failed to adequately traverse the finding of Official Notice because the Applicant supposedly did not state why the noticed fact is not considered to be common knowledge or well-known in the art.[36] However, the Applicant did traverse the finding of Official Notice, stating a reason why the noticed fact that was traversed (acting "without data processing") cannot be considered to be common knowledge. The Applicant explained that the noticed fact specifically contradicts the Joao reference relied upon in the rejection and thus could not be instantly and unquestionably demonstrated.[37] The Applicant's traversal was specific to one aspect of the Official Notice and to the particular reason that it was in error. It was not a general allegation of patentability, but was narrowly tailored to request a showing of documentary evidence. Accordingly, since the Applicant properly traversed the assertion of Official Notice, the Office was required to provide documentary evidence for the rejection to be maintained, but did not do so.

C. Separate argument of claims: Claims 2, 8, 19-29, 31, and 49 are patentable under 35 U.S.C. § 103(a) over Segal, in view of Joao, and further in view of Official Notice.

[36] Office action of Jan. 25, 2007 p. 18
[37] Response of November 13, 2006, pages 16-17

The combination of Segal and Joao fails to disclose a service provider that is not a covered entity either inducing the patient to convert the medical record to a storage format or inducing the patient to update the medical record, as claimed by the present invention in claims 2, 8, 19-29, 31, and 49.

The November 28, 2007, Office action relies upon the teaching of Segal that a patient, with guidance from his or her physician, obtains his or her medical record in a first format (e.g. a hard copy) and converts it into a storage format (e.g. a digital copy).[38] The physician in Segal has access to the medical data of the patient and can thus direct the overall healthcare of the patient.[39] A physician with access to a patient's medical records, as taught in Segal, is a *covered entity*, subject to the restrictions of HIPAA against transferring the resulting records to other medical professionals.[40] In contrast, claims 2, 19-29, and 31 of the present invention specifically require that the service provider that induces the patient to convert the medical records to a storage format is *not* a covered entity. Therefore, the teaching of Segal does not teach or suggest every limitation of the claims.

Similarly, the November 28, 2007, Office action relies upon the teaching of Segal that a patient brings the medical record to his or her physician's office to update it under the guidance of the physician.[41] However, claims 8 and 49 require that the service provider that induces the patient to update the medical record is *not* a covered entity. Therefore, the teaching of Segal does not teach or suggest every limitation of the claims.

Moreover, with respect to claims 2, 8, 19-29, 31, and 49, the service provider of the present invention, which induces the patient to convert and update a medical record, also

[38] Office action of Jan. 25, 2007, page 6
[39] Evidence Appendix, Segal, at page 3, paragraph 0025
[40] Specification, page 11, paragraph 0034
[41] Office action of Nov. 28, 2007, page 7; Evidence Appendix, Segal, at page 12, paragraph 0151

performs other functions, such as storing the medical record created by the patient. In Segal, however, the physician is not a service provider as in the presently claimed invention. Segal neither teaches nor suggests the method and system of the presently claimed invention.

Claim 2 recites, "inducing said patient to convert said medical record to said storage format, wherein said storage format is different from said first format." Claim 19, its dependent claims 20-29, and claim 31 contain essentially the same limitation. Converting the medical record from one format to another is regarded as data processing. Thus, these claims are further distinguished from the prior art by requiring that the patient perform data processing of the medical records obtained from the covered entities. In this way, any necessary data processing is performed, but by the patient instead of by the service provider or a covered entity.

Claim 8 recites, "inducing said patient to update said medical record stored in said memory," and claims 25 and 49 include essentially the same limitation. Thus, these claims are further distinguished from the prior art by requiring that the patient perform data processing of the medical records obtained from the covered entities. Again, any necessary data processing is performed by the patient instead of by the service provider or a covered entity.

D. Claims 33 and 34 are patentable under 35 U.S.C. § 103(a) over Segal, Joao, Official Notice, and Judson.

Claims 33 and 34 are patentable over the combination of references for the same reasons that claims 1-2, 5-8, 11-32, and 35-64 are patentable over Segal in view of Joao and further in view of Official Notice.

E. Claims 9 and 10 are patentable under 35 U.S.C. § 103(a) over Segal, Joao, Official Notice, and Mok.

Claims 33 and 34 are patentable over the combination of references for the same reasons that claims 1-2, 5-8, 11-32, and 35-64 are patentable over Segal in view of Joao and further in view of Official Notice.

IX. CONCLUSION

In conclusion, the Applicant has shown that no proper *prima facie* case of obviousness has been made in the November 28, 2007, Office action.

The combination of Segal and Joao does not teach the method or system of the present invention wherein a medical record is stored without data processing. The November 28, 2007, Office action relies upon Joao for this teaching, yet nothing in Joao, either in any of the embodiments or in the passages relied upon, teaches such a limitation.

The combination of Segal and Joao also does not teach the method or system of the present invention wherein the service provider, who is not a covered entity, induces the patient to convert or update his or her medical records. The November 28, 2007, Office action relies upon Segal for this teaching, yet at most Segal teaches a physician, who is a covered entity, inducing the patient to perform these steps.

Additionally, the combination of references, as relied upon by the November 28, 2007, Office action, is inappropriate because the proposed modification to Segal would change the principle of operation of Segal itself and is improper hindsight reasoning.

Furthermore, the use of Official Notice in place of documentary evidence respecting the transmission of a medical record without data processing is improper because it was used for a teaching that could not be unquestionably demonstrated as well known, did more than to fill the gaps of the prior art, and was unsupported by any reasoning.

Moreover, the use of Official Notice was inappropriate because the Applicant adequately traversed the Official Notice. Documentary evidence was required to maintain the rejection, and was not supplied.

Claims 2, 8, 19-29, 31, and 49 are separately argued, providing additional reasons why they are allowable over the prior art of record.

Therefore, the Applicant respectfully requests that the final rejections of record be reversed and that claims 1-2 and 5-64 be found patentable.

Please charge any fees or credit any overpayment of fees to McAndrews, Held & Malloy, Ltd. Deposit Account No. 13-0017.

Respectfully Submitted,

January 24, 2008

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X. CLAIMS APPENDIX

Claims On Appeal

1. A method for a service provider to obtain a medical record of a patient from a covered entity in a form allowing said service provider to quickly disclose said medical record to a third party without restriction by the Health Insurance Portability and Accountability Act of 1996, the method comprising the following steps carried out by a service provider that is not the patient or a covered entity:

A. inducing said patient to receive said medical record from a covered entity;

B. receiving said medical record from said patient in a storage format, without data processing said medical record;

C. storing said medical record in a memory in a form from which said medical record can be reproduced in said storage format, without data processing said medical record;

D. obtaining agreement in advance with the patient that the service provider shall transmit said medical record to a third party under defined conditions; and

E. transmitting said medical record to a third party when the defined conditions occur, without data processing said medical record.

2. The method of claim 1, further comprising said service provider inducing said patient to obtain possession of said medical record from said covered entity in a first format and said service provider inducing said patient to convert said medical record to said storage format, wherein said storage format is different from said first format.

3. (Canceled)

4. (Canceled).

5. The method of claim 1, wherein said memory is a portable medium.

6. The method of claim 5, wherein said portable medium is an optical disc.

7. The method of claim 1, further comprising retrieving said medical record stored in said memory remotely through a computer communications network.

8. The method of claim 1, further comprising said service provider inducing said patient to update said medical record stored in said memory.

9. The method of claim 1, further comprising said service provider inducing said patient to provide other information that is not a medical record, and storing said other information in said memory.

10. The method of claim 9, wherein said other information comprises information selected from the group consisting of a living will, investment portfolio, life insurance and a credit arrangement.

11. The method of claim 1, wherein said medical record is stored in a hierarchical storage system.

12. The method of claim 11, wherein said medical record is assigned to at least one file folder, said file folder containing medical records sharing at least one common attribute.

13. The method of claim 12, wherein said file folder is assigned to at least one file template, said file template containing file folders sharing at least one common attribute.

14. The method of claim 13, wherein a plurality of said file templates are stored in said storage system to form a general medical and personal information file of said patient.

15. The method of claim 12, wherein said file folder further comprises at least one sub-folder.

16. The method of claim 11, wherein said hierarchical storage system provides hierarchical storage access.

17. The method of claim 14, wherein access to a special file template is on a different basis than access to at least one other file template.

18. The method of claim 17, wherein said special file template is an emergency file template.

19. A method to induce conversion of a medical record of a patient from a covered entity to a form allowing quick disclosure of said medical record to a third party without restriction by the Health Insurance Portability and Accountability Act of 1996, the method comprising:

A. a service provider that is not the patient or a covered entity, inducing said patient to obtain possession of said medical record from a covered entity;

B. said service provider inducing said patient to convert said medical record into a storage format; and

C. said service provider inducing said patient to store said medical record in a memory in said storage forma without data processing said medical record by the service provider.

20. The method of claim 19, further comprising providing said patient a system for converting said medical record into a storage format.

21. The method of claim 20, wherein said system is provided through a computer communications network.

22. The method of claim 20, wherein said system is provided in the form of software.

23. The method of claim 19, wherein said memory is a portable medium.

24. The method of claim 23, wherein said portable medium is an optical disc.

25. The method of claim 19, further comprising said service provider inducing said patient to update said medical record stored in said memory without data processing said medical record by the service provider.

26. The method of claim 19, further comprising said service provider inducing said patient to obtain other information that is not a medical record, and to store said other information in said memory.

27. The method of claim 26, wherein said other information comprises information selected from the group consisting of a living will, investment portfolio, life insurance and a credit arrangement.

28. The method of claim 19, wherein said medical record is stored in a hierarchical storage system.

29. The method of claim 28, wherein said hierarchical storage system provides hierarchical storage access.

30. A medical and personal information system for obtaining and storing a medical record of a patient from a covered entity in a form allowing quick disclosure of said medical record to a third party without restriction by the Health Insurance Portability and Accountability Act of 1996, the system comprising:

A. a communication interface provided at least in part by a service provider that is not the patient or a covered entity, said interface being adapted for inducing said patient to obtain possession of said medical record of said patient from a covered entity; and

B. a data storage device provided at least in part by a service provider that is not the patient or a covered entity, said storage device comprising a memory adapted for storing said medical record in a form from which it can be reproduced in a storage format, wherein said

storage device is configured to store said medical record without data processing said medical record.

31. The system of claim 30, wherein said communication interface is adapted to induce said patient to obtain possession of said medical record in a first format and to induce said patient to convert said medical record to said storage format, wherein said storage format is different from said first format.

32. The system of claim 30, wherein said communication interface is adapted for acquiring said medical record from said patient in said storage format.

33. The system of claim 30, wherein said communication interface is adapted to obtain the agreement of said patient to allow transmission of said medical record to a health care provider under defined conditions.

34. The system of claim 33, wherein communication interface is adapted to obtain said agreement before a defined condition arises.

35. The system of claim 30, wherein said memory is a portable medium.

36. The system of claim 35, wherein said portable medium is an optical disc.

37. The system of claim 30, wherein said communication interface and said data storage device are operatively connected to enable said medical record stored in said memory to be retrieved remotely through a computer communications network.

38. The system of claim 30, wherein said memory is adapted to a hierarchical storage system.

39. The system of claim 38, wherein said hierarchical storage system comprises a general medical information file of said patient.

40. The system of claim 39, wherein said general medical information file comprises a file template.

41. The system of claim 40, wherein said file template comprises a file folder.

42. The system of claim 41, wherein said file folder comprises a sub-folder.

43. The system of claim 38, wherein said data storage device provides hierarchical storage access.

44. The system of claim 40, wherein said general medical information file comprising a special file template accessed on a different basis from said general medical information file.

45. The system of claim 44, wherein said special file template is an emergency file template.

46. The system of claim 44, wherein said special file template is stored in a first memory and said general medical information file is stored in a second memory wherein said first and second memories are different optical discs.

47. The system of claim 30, wherein said memory is adapted for storing other information of the patient that is not a medical record.

48. The system of claim 47, wherein said other information comprises information selected from the group consisting of a living will, an investment portfolio record, a life insurance record and a credit arrangement.

49. The system of claim 30, wherein said communication interface is adapted to induce said patient to update said medical record stored in said memory.

50. The method of claim 1, wherein said medical record is made by the covered entity before said inducing.

51. The method of claim 1, wherein said inducing occurs before the patient obtains possession of the medical record.

52. The method of claim 1, wherein the patient obtains possession of the medical record before said acquiring.

53. The method of claim 1, wherein the patient has a computer with Internet access, and said inducing further comprises said service provider inducing said patient to obtain possession in said patient's computer of said medical record in digital form from a covered entity.

54. The method of claim 1, further comprising said service provider inducing said patient to acquire said medical record in a digital storage format without intervention of any entity or person other than said covered entity.

55. The method of claim 19, wherein said medical record is made by the covered entity before each said inducing.

56. The method of claim 19, wherein said inducing the patient to obtain possession of a medical record occurs before the patient obtains possession of the medical record.

57. The method of claim 19, wherein the patient obtains possession of the medical record before the patient stores the medical record.

58. The method of claim 19, wherein the patient has a computer with Internet access, and said inducing further comprises said service provider inducing said patient to obtain possession in said patient's computer of said medical record in digital form from a covered entity.

59. The method of claim 19, further comprising said service provider inducing said patient to acquire said medical record in a digital storage format without intervention of any entity or person other than said covered entity.

60. The system of claim 30, wherein the communication interface is adapted for inducing said patient to obtain possession of a medical record after said medical record is made by the covered entity.

61. The system of claim 30, wherein the communication interface is adapted for inducing said patient to obtain possession of a medical record before the patient obtains possession of the medical record.

62. The system of claim 30, wherein the communication interface is adapted for obtaining possession of a medical record by the patient before the data storage device stores said medical record.

63. The system of claim 30, wherein the communication interface is adapted for inducing said patient to obtain possession, in a computer possessed by said patient, of said medical record in digital form from a covered entity.

64. The method of claim 30, wherein the communication interface is adapted for inducing said patient to acquire said medical record in a digital storage format without intervention of any entity or person other than said covered entity.

XI. EVIDENCE APPENDIX

A. Joao

B. Segal et al.

C. Mok et al.

D. Judson et al.

Joao

US006283761B1

(12) **United States Patent**
Joao

(10) **Patent No.: US 6,283,761 B1**
(45) **Date of Patent: Sep. 4, 2001**

(54) **APPARATUS AND METHOD FOR PROCESSING AND/OR FOR PROVIDING HEALTHCARE INFORMATION AND/OR HEALTHCARE-RELATED INFORMATION**

(76) Inventor: **Raymond Anthony Joao**, 122 Bellevue Pl., Yonkers, NY (US) 10703

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/476,651**

(22) Filed: **Dec. 31, 1999**

Related U.S. Application Data

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(51) **Int. Cl.**[7] **G09B 19/00**

(52) **U.S. Cl.** 434/236; 434/238; 128/923

(58) **Field of Search** 434/236–238; 128/920, 923

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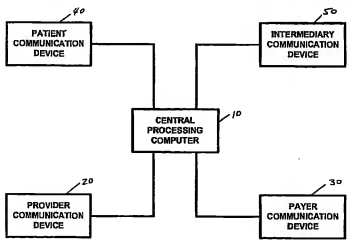
(57) **ABSTRACT**

An improved apparatus and method for providing healthcare information, the apparatus comprising a processor for processing at least one of symptom information and condition information corresponding to a patient, in conjunction with at least one of healthcare information, healthcare theories, healthcare principles, and healthcare research, wherein the processor generates a diagnostic report, and further wherein the diagnostic report contains information regarding at least one of a diagnosis and a possible diagnosis for the at least one of symptom information and condition information. The improvement includes the processor generating a diagnostic report containing a list of possible diagnoses, a transmitter for transmitting the diagnostic report to at least one of a computer and a communication device associated with a healthcare provider, and a receiver for receiving a final diagnosis from the list of possible diagnoses, wherein the final diagnosis is received from the at least one of a computer and a communication device associated with the healthcare provider. The processor generates a claim form for submission to at least one of a healthcare payer and a healthcare insurer.

20 Claims, 24 Drawing Sheets



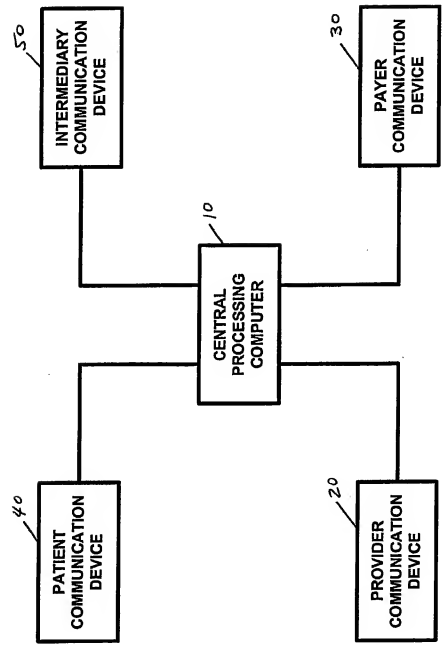

50
INTERMEDIARY COMMUNICATION DEVICE
30
PAYER COMMUNICATION DEVICE
10
CENTRAL PROCESSING COMPUTER
40
PATIENT COMMUNICATION DEVICE
20
PROVIDER COMMUNICATION DEVICE

FIG. 1

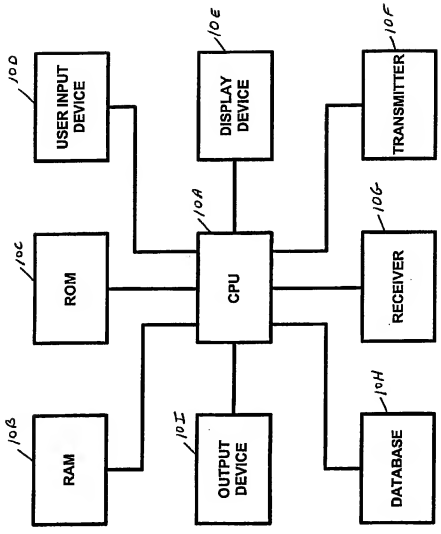

10
100
USER INPUT DEVICE
101
DISPLAY DEVICE
102
TRANSMITTER
103
ROM
104
CPU
105
RECEIVER
106
RAM
107
OUTPUT DEVICE
108
DATABASE

FIG. 2

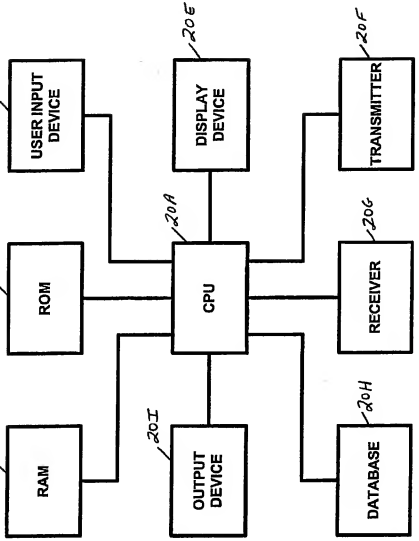

200
USER INPUT DEVICE
206
DISPLAY DEVICE
206
TRANSMITTER
206
ROM
204
CPU
206
RECEIVER
208
RAM
201
OUTPUT DEVICE
204
DATABASE
20

FIG. 3

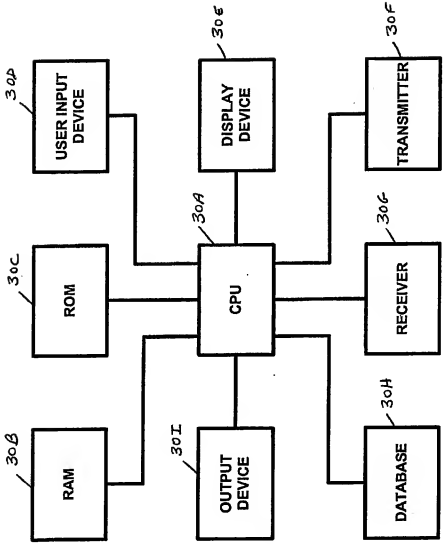

30B
RAM
30C
ROM
30D
USER INPUT DEVICE
30I
OUTPUT DEVICE
309
CPU
30E
DISPLAY DEVICE
30H
DATABASE
30G
RECEIVER
30F
TRANSMITTER
30

FIG. 4

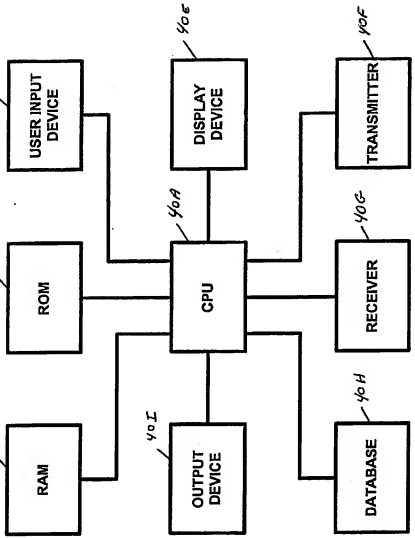
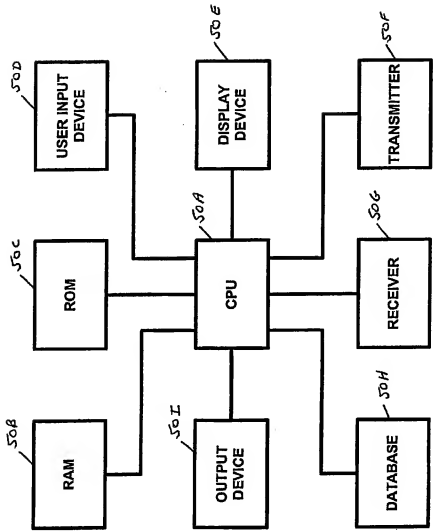

40
CPU
40A
ROM
40C
RAM
40B
USER INPUT DEVICE
40D
DISPLAY DEVICE
40E
TRANSMITTER
40F
RECEIVER
40G
DATABASE
40H
OUTPUT DEVICE
40I

FIG. 5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50A
CPU
50B
RAM
50C
ROM
50D
USER INPUT DEVICE
50E
DISPLAY DEVICE
50F
TRANSMITTER
50G
RECEIVER
50H
DATABASE
50I
OUTPUT DEVICE

FIG. 6

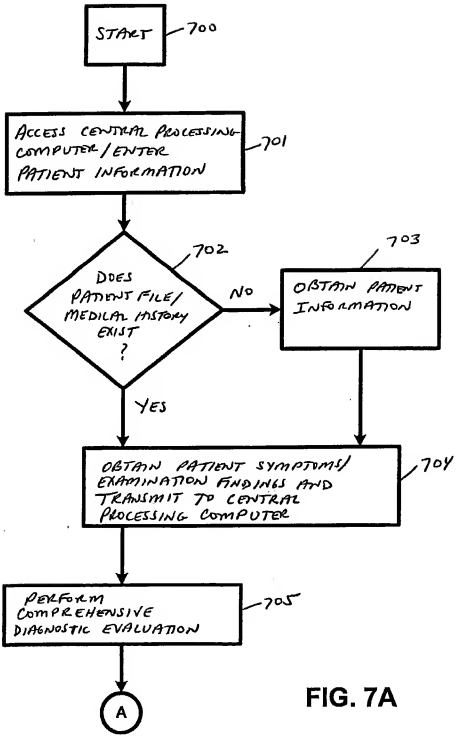
START
700
ACCESS CENTRAL PROCESSING COMPUTER / ENTER PATIENT INFORMATION
701
DOES PATIENT FILE/ MEDICAL HISTORY EXIST ?
702
NO
703
OBTAIN PATIENT INFORMATION
YES
OBTAIN PATIENT SYMPTOMS/ EXAMINATION FINDINGS AND TRANSMIT TO CENTRAL PROCESSING COMPUTER
704
PERFORM COMPREHENSIVE DIAGNOSTIC EVALUATION
705
A

FIG. 7A

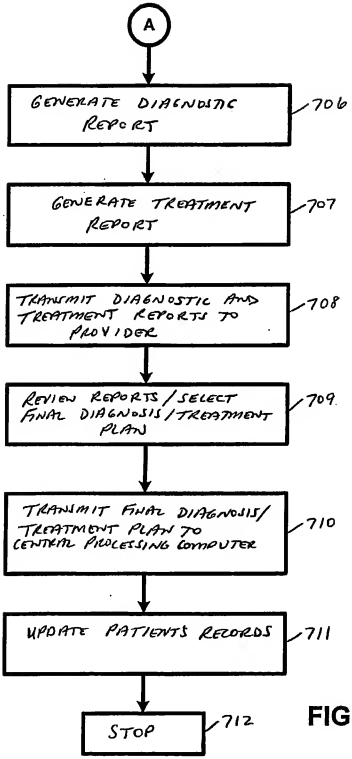
A
GENERATE DIAGNOSTIC REPORT
706
GENERATE TREATMENT REPORT
707
TRANSMIT DIAGNOSTIC AND TREATMENT REPORTS TO PROVIDER
708
REVIEW REPORTS / SELECT FINAL DIAGNOSIS / TREATMENT PLAN
709
TRANSMIT FINAL DIAGNOSIS / TREATMENT PLAN TO CENTRAL PROCESSING COMPUTER
710
UPDATE PATIENTS RECORDS
711
STOP
712

FIG. 7B

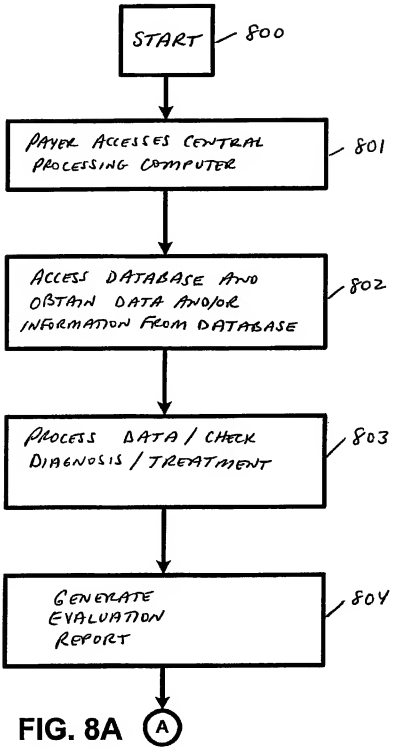
START
800
PAYER ACCESSES CENTRAL PROCESSING COMPUTER
801
ACCESS DATABASE AND OBTAIN DATA AND/OR INFORMATION FROM DATABASE
802
PROCESS DATA / CHECK DIAGNOSIS / TREATMENT
803
GENERATE EVALUATION REPORT
804
A

FIG. 8A

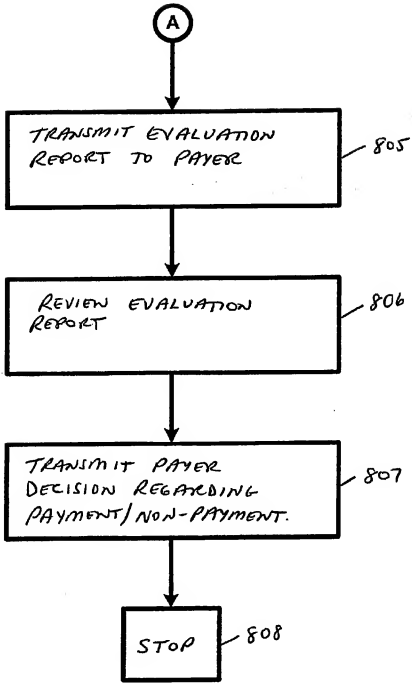
A
TRANSMIT EVALUATION REPORT TO PAYER
805
REVIEW EVALUATION REPORT
806
TRANSMIT PAYER DECISION REGARDING PAYMENT/NON-PAYMENT.
807
STOP
808

FIG. 8B

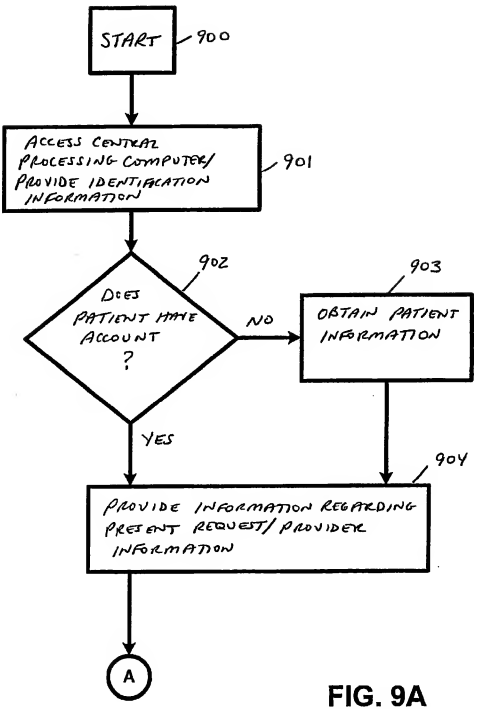
START
900
ACCESS CENTRAL PROCESSING COMPUTER/ PROVIDE IDENTIFICATION INFORMATION
901
DOES PATIENT HAVE ACCOUNT ?
902
NO
OBTAIN PATIENT INFORMATION
903
YES
PROVIDE INFORMATION REGARDING PRESENT REQUEST/ PROVIDER INFORMATION
904
A

FIG. 9A

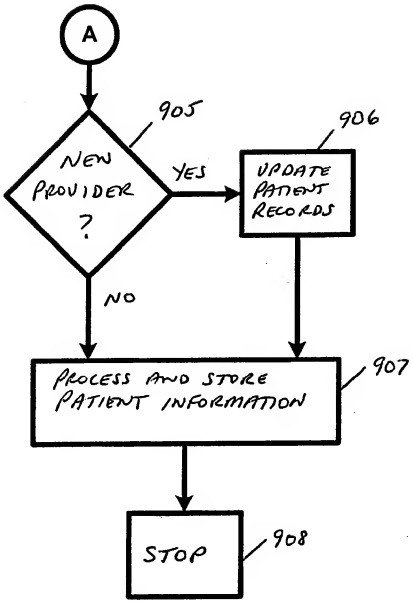
A
905
NEW PROVIDER ?
YES
906
UPDATE PATIENT RECORDS
NO
PROCESS AND STORE PATIENT INFORMATION
907
STOP
908

FIG. 9B

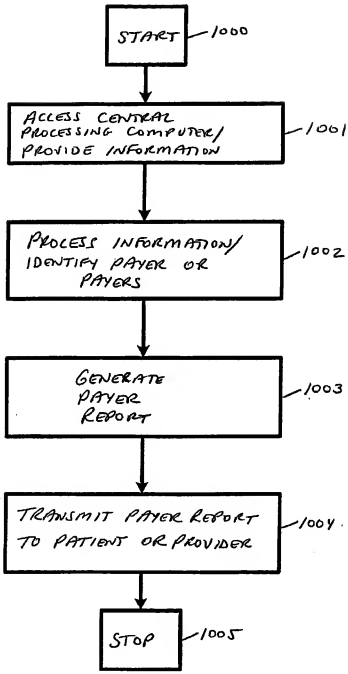
START
1000
ACCESS CENTRAL PROCESSING COMPUTER/ PROVIDE INFORMATION
1001
PROCESS INFORMATION/ IDENTIFY PAYER OR PAYERS
1002
GENERATE PAYER REPORT
1003
TRANSMIT PAYER REPORT TO PATIENT OR PROVIDER
1004
STOP
1005

FIG. 10

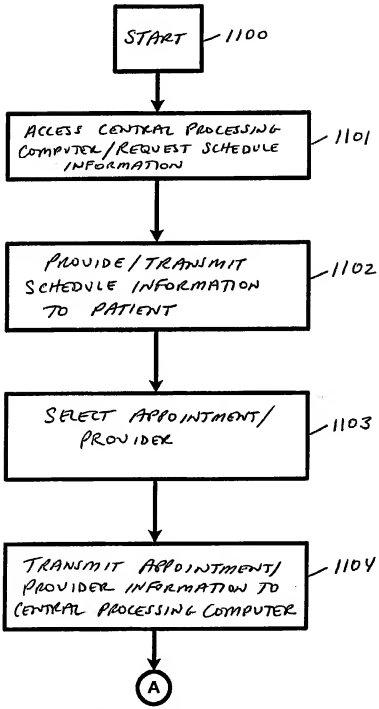
START
1100
ACCESS CENTRAL PROCESSING COMPUTER/REQUEST SCHEDULE INFORMATION
1101
PROVIDE/TRANSMIT SCHEDULE INFORMATION TO PATIENT
1102
SELECT APPOINTMENT/ PROVIDER
1103
TRANSMIT APPOINTMENT/ PROVIDER INFORMATION TO CENTRAL PROCESSING COMPUTER
1104
A

FIG. 11A

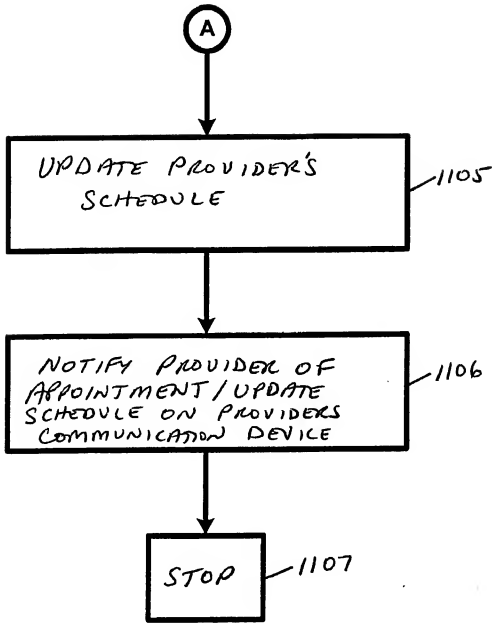
A
UPDATE PROVIDER'S SCHEDULE
1105
NOTIFY PROVIDER OF APPOINTMENT / UPDATE SCHEDULE ON PROVIDERS COMMUNICATION DEVICE
1106
STOP
1107

FIG. 11B

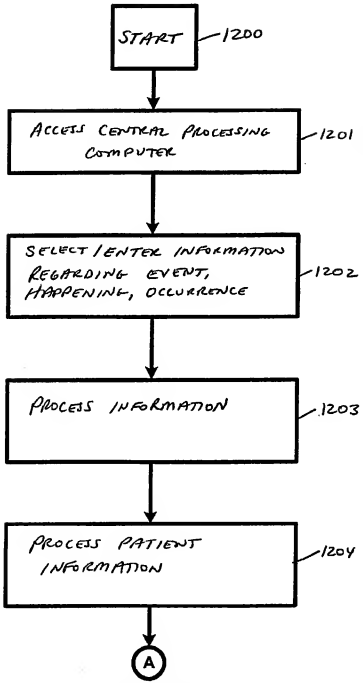
START
1200
ACCESS CENTRAL PROCESSING COMPUTER
1201
SELECT/ENTER INFORMATION REGARDING EVENT, HAPPENING, OCCURRENCE
1202
PROCESS INFORMATION
1203
PROCESS PATIENT INFORMATION
1204
A

FIG. 12A

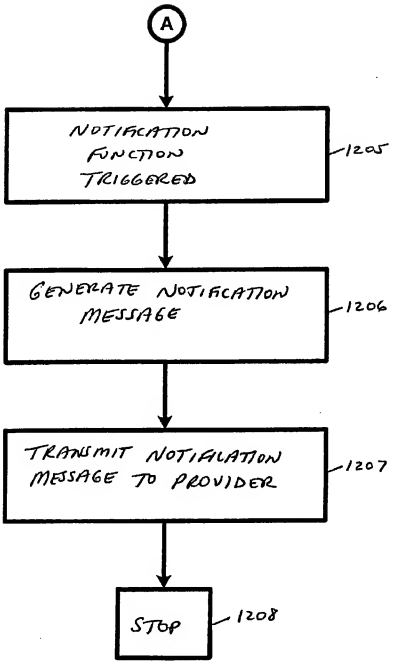
A
NOTIFICATION FUNCTION TRIGGERED
1205
GENERATE NOTIFICATION MESSAGE
1206
TRANSMIT NOTIFICATION MESSAGE TO PROVIDER
1207
STOP
1208

FIG. 12B

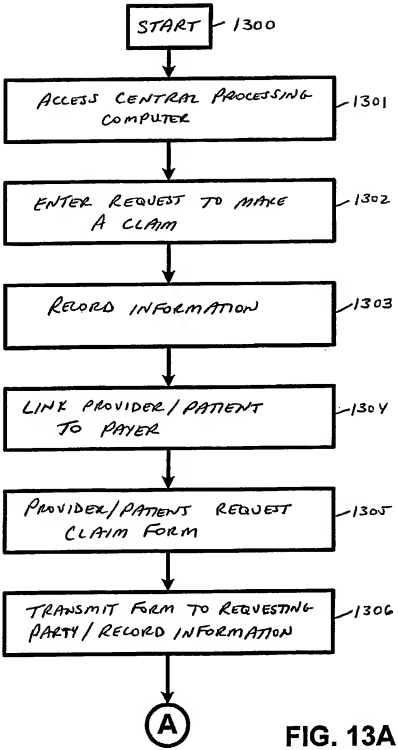
START
1300
ACCESS CENTRAL PROCESSING COMPUTER
1301
ENTER REQUEST TO MAKE A CLAIM
1302
RECORD INFORMATION
1303
LINK PROVIDER/PATIENT TO PAYER
1304
PROVIDER/PATIENT REQUEST CLAIM FORM
1305
TRANSMIT FORM TO REQUESTING PARTY/RECORD INFORMATION
1306
A

FIG. 13A

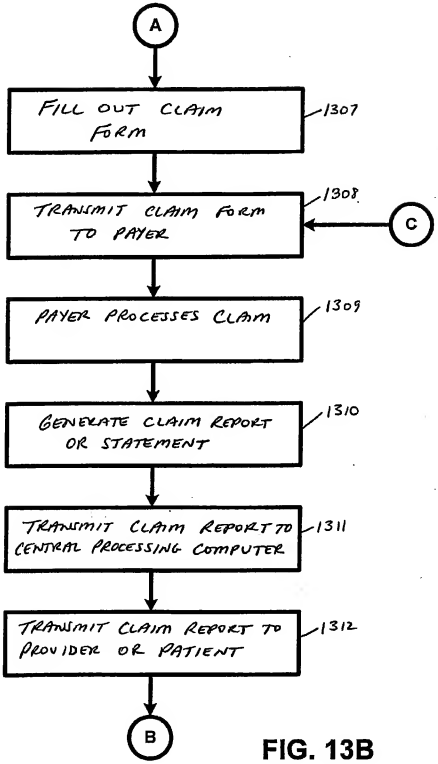
A
FILL OUT CLAIM FORM
1307
TRANSMIT CLAIM FORM TO PAYER
1308
C
PAYER PROCESSES CLAIM
1309
GENERATE CLAIM REPORT OR STATEMENT
1310
TRANSMIT CLAIM REPORT TO CENTRAL PROCESSING COMPUTER
1311
TRANSMIT CLAIM REPORT TO PROVIDER OR PATIENT
1312
B

FIG. 13B

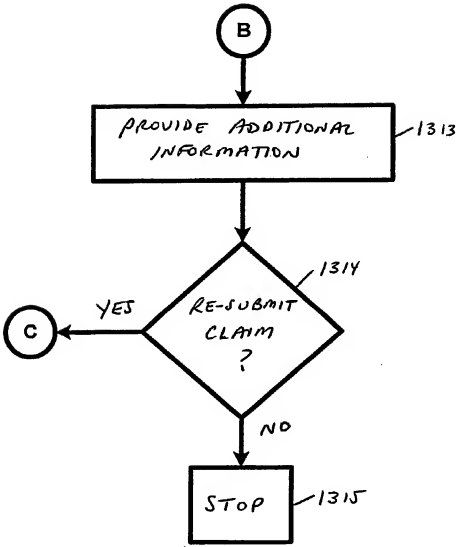
B
PROVIDE ADDITIONAL INFORMATION
1313
1314
RE-SUBMIT CLAIM ?
YES
C
NO
STOP
1315

FIG. 13C

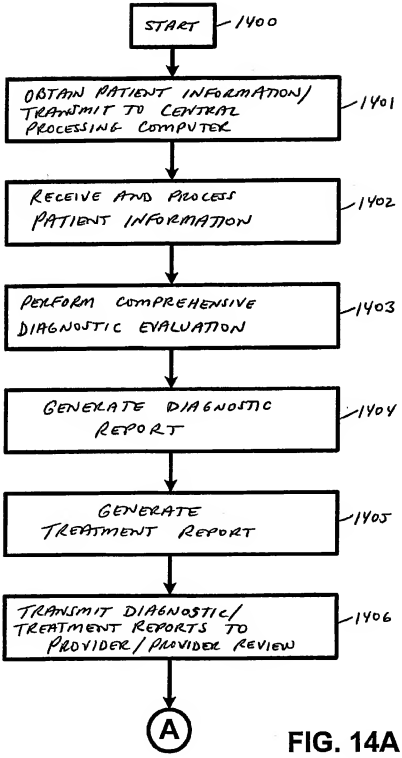
START
1400
OBTAIN PATIENT INFORMATION/ TRANSMIT TO CENTRAL PROCESSING COMPUTER
1401
RECEIVE AND PROCESS PATIENT INFORMATION
1402
PERFORM COMPREHENSIVE DIAGNOSTIC EVALUATION
1403
GENERATE DIAGNOSTIC REPORT
1404
GENERATE TREATMENT REPORT
1405
TRANSMIT DIAGNOSTIC/ TREATMENT REPORTS TO PROVIDER/PROVIDER REVIEW
1406
A

FIG. 14A

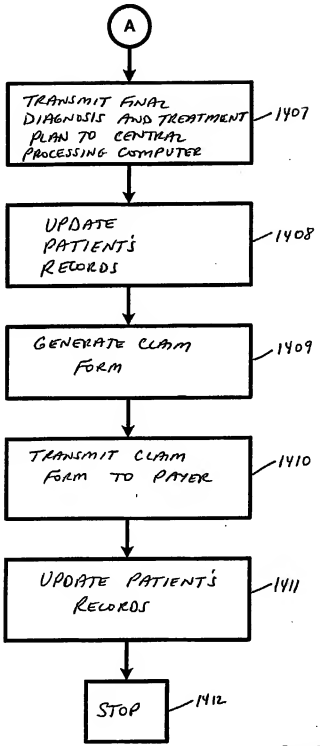
A
TRANSMIT FINAL DIAGNOSIS AND TREATMENT PLAN TO CENTRAL PROCESSING COMPUTER
1407
UPDATE PATIENT'S RECORDS
1408
GENERATE CLAIM FORM
1409
TRANSMIT CLAIM FORM TO PAYER
1410
UPDATE PATIENT'S RECORDS
1411
STOP
1412

FIG. 14B

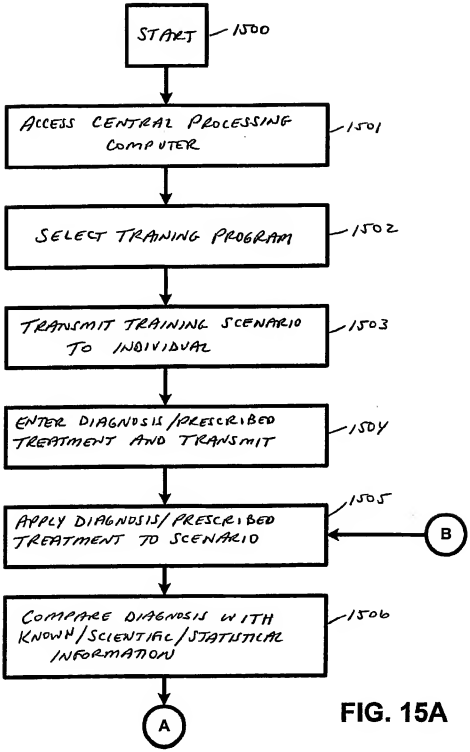
START
1500
ACCESS CENTRAL PROCESSING COMPUTER
1501
SELECT TRAINING PROGRAM
1502
TRANSMIT TRAINING SCENARIO TO INDIVIDUAL
1503
ENTER DIAGNOSIS/PRESCRIBED TREATMENT AND TRANSMIT
1504
APPLY DIAGNOSIS/PRESCRIBED TREATMENT TO SCENARIO
1505
B
COMPARE DIAGNOSIS WITH KNOWN/SCIENTIFIC/STATISTICAL INFORMATION
1506
A

FIG. 15A

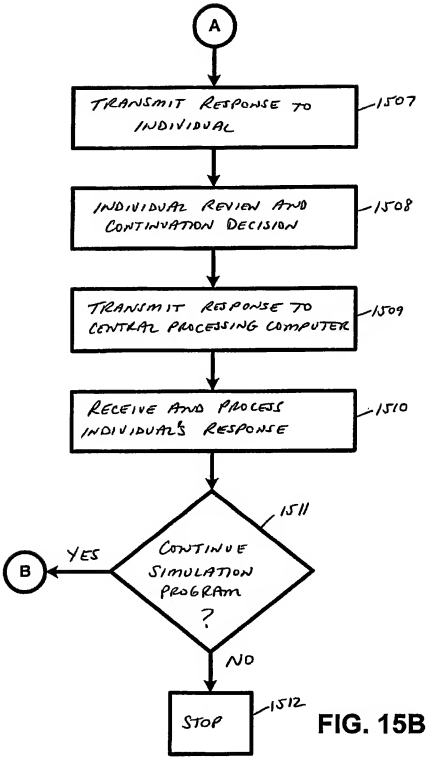
A
TRANSMIT RESPONSE TO INDIVIDUAL
1507
INDIVIDUAL REVIEW AND CONTINUATION DECISION
1508
TRANSMIT RESPONSE TO CENTRAL PROCESSING COMPUTER
1509
RECEIVE AND PROCESS INDIVIDUAL'S RESPONSE
1510
CONTINUE SIMULATION PROGRAM ?
1511
YES
B
NO
STOP
1512

FIG. 15B

APPARATUS AND METHOD FOR PROCESSING AND/OR FOR PROVIDING HEALTHCARE INFORMATION AND/OR HEALTHCARE-RELATED INFORMATION

RELATED APPLICATIONS

This is a continuatioo-in-part application of U.S. patent application Ser. No. 09/162,889, filed Sep. 29, 1998, which is a continuation application of U.S. patent application Ser. No. 08/600,771, filed Feb. 13, 1996, now U.S. Pat. No. 5,961,332, which is a divisional application of U.S. patent application Ser. No. 07/941,413, filed Sep. 8, 1992, abandoned.

FIELD OF THE INVENTION

The present inventioo pertains to an apparatus and a method for processing and/or for providing healthcare information aod/or healthcare-related information and, in particular, to an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information for a variety of healthcare and healthcare related applications.

BACKGROUND OF THE INVENTION

Each year, tens of millions of individuals seek or need the assistance of healthcare professionals. In order to perform proper diagnoses and to prescribe appropriate treatments, healthcare professional or providers typically rely on information which is obtained from patients, relatives of patients, previous providers, and/or healthcare facility and/or hospital staff members. The need to have accurate and/or up-to-date data and/or information, in providing healthcare services and/or healthcare-related services, cannot be emphasized enough.

Stories constantly emerge about patients receiving the wrong treatments, having the wrong surgical procedures performed on themselves, receiving a drug or drugs which fatally and/or otherwise adversely interact with another drug or drugs, etc., with stories going on and on. Recently, it has been estimated that between 44,000 and 98,000 individuals die, in the United States alone, as the result of errors or mistakes made by doctors, healthcare providers, and/or healthcare facility workers. There is no doubt that many of these deaths result from inaccurate and/or erroneous information and/or the lack of the availability of correct and/or up-to-date information.

Another problem lies with the fact that the main source of patient information, medical histories, family histories, etc., upon which doctors or providers may base their diagnoses aod/or treatments, are patients who usually supply this information on questionnaires or forms just prior to seeing the healthcare provider and/or during a preliminary interview with the provider. In this regard, information obtained from these questionnaires or forms, as well as from these preliminary interviews with the providers, may not necessarily result in sufficient, comprehensive, and/or accurate, information being obtained regarding the patient. Further, there is no guarantee that the same information will be provided, in a uniform manner, to a next or different provider. As a result, patieot information may not be uniformly distributed and/or be available to providers at the point of treatment and/or otherwise.

Another problem which exists in the current healthcare system is that doctors or other providers do not always have the latest information and/or research material available to them prior to, aod/or during, the diagnosis and/or treatment process.

It is also no secret that healthcare costs are rising at ever-increasing rates and that insurance companies and other healthcare payers expend great resources in processing and reconciling treatment claims and/or claims for healthcare services and/or benefits. Typically, these insurance and/or benefits claims take place in a paper-based environmeot and, as a result are slow and inefficient. Fraudulent claims and/or claims which cannot be verified pose another major problem for healthcare payers and insurance companies. These problems only serve to add to the growing costs of healthcare, delayed treatments, and a general dissatisfaction with the current healthcare system.

Another problem lies in making up-to-date training materials conveniently available to providers in order to allow providers to remain current with state-of-the-art information and training techniques.

The list of problems with the current healthcare system goes on and on. In view of the above, there is a great need for an apparatus and a method for providing healthcare information and/or healthcare-related information to the various providers, payers, patients, third party individuals, and/or insurance brokers, agents and/or other intermediaries, which overcomes the shortcomings of prior art.

SUMMARY OF THE INVENTION

The present invention provides an apparatus and methods for providing healthcare information and/or healthcare-related information which overcomes the shortcomings of the prior art.

The present invention is directed to an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information and, in particular, to an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information for a variety of healthcare and healthcare related applications.

The apparatus and method of the present invention facilitates the creation and management of a comprehensive healthcare processing system which can manage patient and client records, doctor and other provider records, healthcare insurance and/or payer records, and thereby provide an apparatus, system and methods for providing a variety and a multitude of healthcare information processing applications, processes and services.

The present invention facilitates improved healthcare quality, efficient information collection, processing and dissemination, efficient diagnosis and treatment, cost efficiency, cost containment, as well as many other benefits and advantages as will be described herein. The apparatus and method of the present invention also facilitates the distribution and management of healthcare insurance, life insurance, disability insurance, as well as claims processing related thereto.

The present invention also provides an apparatus and a method for providing a comprehensive processing system which incorporates data and/or information from any combination and/or all of the participants in the healthcare field, including patients, providers, payers or insurance companies, and/or brokers, agents and/or other intermediaries who act on behalf of any of the above-identified persons or entities.

The apparatus of the preseot inventioo includes a central processing computer or central processing computer system which can be a network or server computer. The apparatus also includes a healthcare provider communication device or computer which is associated with a healthcare provider

such as a healthcare professional, a hospital, a clinic, and/or any other provider of services described herein. The healthcare provider computer(s) can communicate with, and operate in conjunction with, the central processing computer and/or any of the other computers and/or computer systems or communication devices described herein.

The apparatus also includes a healthcare payer communication device or computer which is associated with a healthcare payer such as a healthcare insurer, insurance company, health maintenance organization, a clinic, and/or any other payer of healthcare services and products described herein. The healthcare payer computer(s) can communicate with, and operate in conjunction with, central processing computer and/or any of the other computers and/or computer systems or communication devices described herein.

The apparatus also includes a patient or individual user communication device or computer which is associated with a healthcare patient such as a patient, user, or client who seeks or who is provided with healthcare and/or related services, products and/or related information. The patient computer(s) can communicate with, and operate in conjunction with, central processing computer and/or any of the other computers and/or computer systems described herein.

The apparatus also includes an intermediary communication device or computer which is associated with an intermediary, a broker, an agent, and/or any other individual and/or entity, that can utilize the present invention in order to act for and/or on behalf of any other individual, party, or entity, described herein. The intermediary computer(s) can communicate with, and operate in conjunction with, central processing computer and any of the other computers and/or computer systems described herein.

Each of the central processing computer(s), the provider computer(s), the payer computer(s), the patient computer(s), and/or the intermediary computer(s), can transmit information to, as well as receive information from, any of the computers described herein. In this regard, each of the computers can communicate with, process information from, and/or share data and/or information with, each other and/or any other computer or computers described herein and/or utilized in conjunction with the present invention. In this manner, data and/or information transfer between any of the computers can take place in a bi-directional manner.

The central processing computer(s), the provider computer(s), the payer computers(s), the patient computer (s), and the intermediary computer(s), can communicate with one another, and/or be linked to one another, over a communication network, a telecommunication network, a telephone network, a line-connected network, and/or a wireless communication network.

The present invention can be utilized on, or over, the Internet and/or the World Wide Web and/or on, or over, any other communication network or system, including, but not limited to, a communication network or system, a telecommunication network or system, a telephone communication network or system, a cellular communication network or system, a wireless communication network or system, a wireless Internet network or system, a wireless World Wide Web network or system, a line or wired communication network or system, a digital communication network or system, a personal communication network or system, a personal communication services (PCS) network or system, a satellite communication network or system, a broad band communication network or system, a low earth orbiting (LEO) satellite network or system, a public switched telephone network or system, a telephone communication network or system, a radio communication network or system, and/or any other communication network or system, and/or any combination of the above communication networks or systems.

The apparatus and method of the present invention can utilize electronic commerce technologies and security methods, techniques and technologies, in any and/or all of the instances of data and/or information processing, and/or data and/or information transmission described herein.

Each of the central processing computer(s), as well as each of the computers or communication devices associated with each of the herein-described users, patients, providers, payers, and/or intermediaries, can include a central processing unit or CPU, a random access memory device(s) (RAM), a read only memory device(s), and a user input device. Each of the central processing computer(s), as well as each of the computers or communication devices associated with each of the herein-described users, patients, providers, payers, and/or intermediaries, can also include a display device, a transmitter(s), a receiver, a database(s), and an output device. The database(s) can contain any and/or all of the data and or information which is needed to perform the various processing methods, services, functions and/or operations, described herein.

The apparatus and method of the present invention can be utilized in numerous preferred embodiments in order to provide a vast array of healthcare and healthcare-related services for any one or more of the various parties described herein. Any patient, user, provider, payer, and/or intermediary, may utilize the present invention in the same, similar and/or analogous manner.

The present invention can be utilized for a number of applications, including, but not limited to, determining and/or ascertaining a medical diagnosis, verifying and/or checking a diagnosis or treatment, or performing a self-diagnosis. The present invention can be utilized by any of the parties described herein.

The present invention can be utilized to create and maintain comprehensive patient databases which can be accessed via a network environment and/or otherwise, to perform healthcare and/or healthcare-related diagnoses, to provide healthcare and/or healthcare-related expected prognoses, to provide healthcare and/or healthcare-related treatment plans or programs, and/or to provide healthcare and/or healthcare-related treatment progress reports and/or evaluations.

The present invention can also be utilized in order to provide training and continuing education services for healthcare and/or healthcare-related professionals, to provide healthcare, healthcare-related, and/or wellness information, to provide information about healthcare and/or healthcare-related patient, providers, payers, and/or intermediaries, to provide scheduling management services for providers, to provide notification services for patients, providers, payers and/or intermediaries, and/or any other parties described herein, and/or to locate providers, payers and/or intermediaries.

The present invention can also be utilized in order to provide healthcare and/or healthcare-related claim processing services, claims submissions, claim processing, claim status checking, and claim reconciliation, claim fraud prevention, treatment evaluation, healthcare and/or healthcare insurance policy generation, management and administration, provider, payer and/or intermediary evaluation, drug and/or treatment interactivity, treatment, medication and/or organ availability and/or notification

services, patient, provider, payer, intermediary and/or third party, notification services. The present invention can also be utilized as a clearinghouse for facilitating the offering, selling, buying, trading, and/or other commerce and/or transactions, involving healthcare and/or healthcare-related services, products and/or goods.

The various computers and/or communication devices can be utilized to transmit and/or to receive transmissions, information, messages, and/or notification messages and/or signals, to and/or between, the respective parties associated with the respective computers and/or communication devices. The transmission of information, messages, and/or notification messages and/or signals can be effected via any one or more of e-mail messages, telephone messages, beeper or pager messages, physical mail delivery, electronic data transmission, and/or can be made via any other suitable and/or appropriate communication method and/or technique.

The present invention can be utilized in order to perform a diagnosis of a sickness, illness and/or other condition. The present invention can also be utilized to ensure that a proper treatment and/or procedure is performed on the patient, and/or to ensure that a subsequent treatment and/or treatments are performed as prescribed. The present invention can also be utilized in order to prevent medical and/or surgical mistakes, mishaps and/or other instances when improper treatment could occur.

The present invention can also be utilized to allow a subsequent care provider to re-evaluate a patient's condition and/or records and to seek additional assistance for the patient, and/or to perform a separate and independent assessment and/or diagnosis of the patient.

The present invention can also be utilized in order to access a patient's or a client's record(s) and input information concerning the treatment and/or procedure to be performed. Thereafter, the present invention can provide notification to a healthcare professional that the treatment and/or procedure may be a prescribed treatment or procedure or a non-prescribed treatment and/or procedure.

Any and/or all processing described herein can be performed in conjunction with a patient's medical history, family history, allergic conditions information, and/or with any other information deemed important and/or essential in the an individual's healthcare diagnoses and/or treatments.

The present invention can also be utilized to perform treatment evaluations and/or treatment monitoring so as to allow for an evaluation and/or a monitoring of treatment and/or for providing training for healthcare providers and/or professionals. The present invention can also be utilized in order to allow payer and/or insurance companies to evaluate treatments, treatment plans, treatment progress, and/or any other evaluations and/or verifications for healthcare claims processing.

The present invention can provide treatment evaluation and/or monitoring for healthcare payers which can be utilized for performing claims processing, provider evaluations, patient evaluations, and/or any other useful and/or desired purpose.

The present invention can also be utilized to create and maintain a comprehensive patient healthcare database which can be accessed by any provider, payer, intermediary, and/or other party or user, in order to access the patient's healthcare files and/or records. The comprehensive database can provide data and/or information source which can be accessed by any provider, from anywhere in the world, and at any time, in order to obtain information about a patient in his, her, or its care. Payers can also utilize the comprehensive database in order to ascertain payment eligibility, the existence of pre-existing conditions and/or to obtain any other useful information.

The present invention can also be utilized in order to find and/or to locate providers and/or payers of, and for, respectively, various healthcare treatments, healthcare services and/or healthcare goods or products and/or healthcare-related goods or products. The present invention can also be utilized to find a payer or insurance company for providing desired coverage and/or for paying for certain treatments and/or procedures.

The present invention can also be utilized to find and/or locate supplies, body organs, blood, medications, and/or any other goods, products, and/or supplies, etc. The present invention can also be utilized by intermediaries, such as insurance brokers, who need to find certain insurance companies and/or payers who meet the needs of certain patients and/or clients, and/or other individuals and/or third parties.

The present invention can also be programmed to provide notification of the availability of a provider, the emergence of a patient in need of a certain care, the availability of a payer or an insurance company to offer a policy or a certain policy, the availability of a healthcare facility to provide certain care, the availability of certain supplies, a body organ, a blood type, an expiration of an insurance policy (i.e. healthcare insurance, life insurance, disability insurance, etc.,) and/or the occurrence of any event which may be of interest to any of the patients, users, providers, payers, and/or intermediaries, described herein.

The present invention can also be utilized to schedule appointments with any of the patients, providers, payers, and/or intermediaries, described herein.

The present invention can be utilized by intermediaries, such as, but not limited to brokers, insurance brokers, agents, and others, in order to service their respective clients. The present invention can be utilized to prepare policy quotes, to compare available policies, to generate and/or underwrite policies, and to service policy claims. In this, manner, the present invention can provide a platform for allowing a broker to provide improved services to his or her clients while also providing for a more paperless working relationship.

The present invention can also be utilized to process healthcare claims. The present invention can allow any of the patients, providers, payers, users, and/or intermediaries, to file claims with the respective party electronically and/or otherwise. The present invention can provide for the processing, tracking and reconciliation, of any and/or all healthcare claims and/or healthcare-related claims.

The present invention can also be utilized to notify any party described herein, as well as any third parties, regarding any event, happening, occurrence, and/or any aspect of any claim submission and/or processing activities.

The present invention can also provide for automatic claim submission via the central processing computer once a final diagnosis and treatment has been prescribed by a provider and/or upon the occurrence of an examination and/or the administration of a treatment.

The present invention can also be utilized, in the manner described above in connection with claiming healthcare insurance benefits, disability insurance benefits, and/or life insurance benefits.

The present invention can also be utilized to administer and/or maintain financial accounts for, and/or on behalf of,

any of the patients, users, providers, payers, and/or intermediaries, described herein. The present invention can maintain detailed records of any and/or all of such transfers and/or transactions and provide periodic account statements to the respective parties maintaining accounts with the present invention.

The apparatus and method of the present can also be utilized as a healthcare training simulator for any of the providers, healthcare providers, healthcare professionals, and/or other providers described herein. The present invention can also be utilized by any user and/or individual wishing to learn about a certain healthcare field or topic. Data and/or information collected and/or stored by the apparatus, which relates to symptoms and/or conditions, as well as responses to treatments, can be utilized in order to present realistic and confidential training scenarios.

The present invention can also provide for the security and/or the confidentiality of any and/or all of the data and/or information stored by, and/or processed by, same. Identification cards can also be utilized so as to store pertinent information for any of the respective parties so as to provide the respective party with access to various data and/or information and/or any processing functionality which can be provided by the present invention.

The present invention can also utilize intelligent agents, software agents, and/or mobile agents, which agents can be programmed to act for, and/or on behalf of, any of the parties described herein. The intelligent agent(s) can act on behalf of the respective party in various related interactions and/or other activities which are described as being performed herein and/or which may be incidental and/or related thereto. Therefore, the present invention also provides an agent-based apparatus and method for providing healthcare information and/or healthcare-related information.

The apparatus of the present invention can also be programmed to be self-activating and/or activated automatically. The apparatus of the present invention can also be programmed in order to automatically generate and/or transmit any of the e-mails, electronic message transmissions, electronic notification transmissions, and/or any of the communications, described herein, between any of the parties which utilize the present invention.

The data and/or information, described as being stored in the various databases utilized by the respective computers and/or communication devices can be continuously updated so as to store the latest values for the data and/or information and can be stored and be made available for future processing routines.

Any and/or all of the data and/or information described herein as being stored in any of the various databases, can be linked via relational database techniques and/or via any appropriate database management techniques. The data and/or information can be updated via inputs from any of the computers and/or communication devices described herein, and/or external computers or communication devices, in real-time, and/or via dynamically linked database management techniques. The data and/or information which is stored in the various databases can be linked via any suitable data linking techniques such as, for example, dynamically linked lists (DLLs), linked lists, and object links embedded (OLE's).

Accordingly, it is an object of the present invention to provide an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information.

It is another object of the present invention to provide an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information, in a network environment.

It is still another object of the present invention to provide an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information, which can be utilized in a number of healthcare and/or healthcare-related applications.

It is yet another object of the present invention to provide an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information, which provides and/or facilitates the creation and management of a comprehensive healthcare processing system.

It is another object of the present invention to provide an apparatus and a method for performing healthcare diagnoses.

It is still another object of the present invention to provide an apparatus and a method for performing healthcare diagnoses, in a network environment.

It is yet another object of the present invention to provide an apparatus and a method for prescribing healthcare treatments.

It is another object of the present invention to provide an apparatus and a method for prescribing healthcare treatments, in a network environment.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can incorporate data and/or information from any combination and/or all of the participants in the healthcare field, including patients, users, providers, payers or insurance companies, and/or brokers, agents and/or other intermediaries who act on behalf of any of the above-identified persons or entities.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized by a healthcare professional to verify and/or to check a diagnosis.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized by an individual to perform a self-diagnosis.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to create and/or to maintain a comprehensive patient database which can be accessed to perform any one or more of healthcare and/or healthcare-related diagnoses, to provide healthcare and/or healthcare-related expected prognoses, to provide healthcare and/or healthcare-related treatment plans or programs, and/or to provide healthcare and/or healthcare-related treatment progress reports and/or evaluations.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized as a healthcare training simulator.

It is another object of the present invention to provide an apparatus and a method for providing healthcare training.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide scheduling management services for providers, payers, providers, users, and/or intermediaries.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide notification services for patients, providers, payers, users, and/or intermediaries,

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to locate providers, payers, patients, users, and/or intermediaries.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide healthcare claim processing services.

It is yet another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide healthcare claim processing services, including any one or more of claims submissions, claim processing, claim status checking, claim reconciliation, and/or claim fraud prevention.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide healthcare treatment evaluation.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide healthcare insurance policy generation, policy management, and/or policy administration.

It is yet another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide provider, payer, and/or intermediary evaluation.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide information regarding drug and/or treatment interactivity, and/or treatment, medication, and/or organ availability.

It is another object of the present invention to provide an apparatus which can be utilized as a clearinghouse for facilitating the offering, selling, buying, trading, and/or other commerce and/or transactions, involving healthcare and/or healthcare-related services, products and/or goods.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to ensure that a proper treatment(s) or procedure(s) is prescribed for a patient and/or that a proper treatment and/or procedure is administered to, or performed on, a patient.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to access a patient's or a client's record(s) and/or to obtain information concerning a treatment and/or a procedure to be performed.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide healthcare diagnoses in conjunction with a patient's medical history, family history, allergic conditions information, and/or with any other information deemed important and/or essential in the an individual's healthcare diagnosis and/or treatment.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to allow payers and/or insurance companies to evaluate treatments, treatment plans, treatment progress, and/or any other evaluations and/or verifications, for healthcare claims processing.

It is yet another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to allow providers or payers to evaluate treatments, treatment plans, treatment progress, and/or any other evaluations and/or verifications, claims processing for providing healthcare and/or related services.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to find and/or locate supplies, body organs, blood., medications, and/or any other goods, products, and/or supplies, etc.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to find and/or locate a payer or insurance company for providing desired coverage and/or for paying for certain treatments and/or procedures.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized by intermediaries, such as insurance brokers, to find and/or locate insurance companies and/or payers who meet the needs of certain parties.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be programmed to provide notification of the availability of a provider, the emergence of a patient in need of a certain care, the availability of a payer or an insurance company to offer a policy or a certain policy, the availability of a healthcare facility to provide certain care, the availability of certain supplies, a body organ, a blood type, an expiration of an insurance policy, and/or the occurrence of any event which may be of interest to patients, users, providers, payers, and/or intermediaries.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to prepare insurance policy quotes, compare available policies, generate policies, and service policy claims.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide for automatic healthcare claim submission.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to provide for automatic healthcare claim submission once a final diagnosis has been determined and/or a treatment has been prescribed.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to claim healthcare insurance benefits, disability insurance benefits, and/or life insurance benefits.

It is yet another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to administer and/or maintain financial accounts for, and/or on behalf of, any of the patients, users, providers, payers, and/or intermediaries, described herein.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can provide for the security and/or the confidentiality of any data and/or information concerning patients, users, providers, payers, and/or intermediaries.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized in conjunction with identification cards which are utilized to store information regarding patients, providers, payers, users, and/or intermediaries.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information

which can be utilized in conjunction with intelligent agents, software agents, and/or mobile agents.

It is yet another object of the present invention to provide an apparatus and a method for providing healthcare information which can be programmed to be self-activating and/or activated automatically.

It is another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized to automatically generate and/or transmit any of the e-mails, electronic message transmissions, electronic notification transmissions, and/or any of the communications, described herein, between any of the parties which utilize the present invention.

It is still another object of the present invention to provide an apparatus and a method for providing healthcare information which can be utilized in conjunction with various electronic commerce technologies and/or security methods, techniques and technologies.

Other objects and advantages of the present invention will be apparent to those skill in the art upon a review of the Description of the Preferred Embodiment, taken in conjunction with the Drawings which follow.

BRIEF DESCRIPTION OF THE DRAWINGS

In the Drawings:

FIG. 1 illustrates a preferred embodiment of the present invention, in block diagram form;

FIG. 2 illustrates the central processing computer of FIG. 1, in block diagram form;

FIG. 3 illustrates the provider communication device of FIG. 1, in block diagram form;

FIG. 4 illustrates the payer communication of FIG. 1, in block diagram form;

FIG. 5 illustrates the patient communication device of FIG. 1, in block diagram form;

FIG. 6 illustrates the intermediary communication device of FIG. 1, in block diagram form;

FIGS. 7A and 7B illustrate a preferred embodiment method of using the present invention, in flow diagram form;

FIGS. 8A and 8B illustrate another preferred embodiment method of using the present invention, in flow diagram form;

FIGS. 9A and 9B illustrate still another preferred embodiment method of using the present invention, in flow diagram form;

FIG. 10 illustrates yet another preferred embodiment method of using the present invention, in flow diagram form;

FIGS. 11A and 11B illustrate another preferred embodiment method of using the present invention, in flow diagram form;

FIGS. 12A and 12B illustrate still another preferred embodiment method of using the present invention, in flow diagram form;

FIGS. 13A, 13B and 13C illustrate yet another preferred embodiment method of using the present invention, in flow diagram form;

FIGS. 14A and 14B illustrate another preferred embodiment method of using the present invention, in flow diagram form; and

FIGS. 15A and 15B illustrate another preferred embodiment method of using the present invention, in flow diagram form.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is directed to an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information and, in particular, to an apparatus and a method for processing and/or for providing healthcare information and/or healthcare-related information for a variety of healthcare and healthcare related applications. The apparatus and method of the present invention facilitates the creation and management of a comprehensive healthcare processing system which can manage patient and client records, doctor and other provider records, healthcare insurance and/or payer records, and thereby provide an apparatus, system and methods for providing a variety and a multitude of healthcare information processing applications, processes and services. The present invention facilitates improved healthcare quality, efficient information collection, processing and dissemination, efficient diagnosis and treatment, cost efficiency, cost containment, as well as many other benefits and advantages as will be described herein.

The apparatus and method of the present invention also facilitates the distribution and management of healthcare insurance, life insurance, disability insurance, as well as claims processing related thereto.

The present invention also provides an apparatus and a method for providing a comprehensive processing system which incorporates data and/or information from any combination and/or all of the participants in the healthcare field including, but not limited to, patients and those seeking healthcare, healthcare providers, doctors, including medical doctors, surgeons, physicians, dentists, psychologists, optometrists, podiatrists, osteopaths, chiropractors, pharmacists, therapists, physical therapists, respiratory therapists, nurses, healthcare aids, nutritionists, and/or any other person, individual and/or professional who can provide healthcare, healthcare-relate, wellness and/or wellness-related services and/or products, insurance companies, healthcare insurance companies, disability insurance companies, casualty insurance companies, health maintenance organizations, healthcare providers, and any other payer and/or provider of healthcare services and/or products, healthcare claims processing centers, healthcare insurance brokers and/or agents , and/or any other third party and/or intermediary who or which acts on behalf of another and/or assists in to providing of healthcare and/or related services.

Applicant hereby incorporates by reference herein the subject matter of U.S. patent application Ser. No. 09/162,889 which teaches an apparatus and method for processing healthcare data. Applicant also hereby incorporates by reference herein the subject matter of U.S. Pat. No. 5,961,332 which teaches an apparatus for processing psychological data and method of use thereof.

As used herein, the terms "individual", "patient", "client", "user" or the like, or their plural forms, refers to any person, individual, patient, and/or client who uses the present invention, and/or who seeks and/or who receives healthcare services, healthcare-related services, healthcare-related information, and/or any of the other services and/or products provided by the present invention.

As used herein, the terms "doctor", "healthcare provider", "provider", "therapist", "healthcare information specialist", etc., or their plural forms, refers to any medical doctor, including any and all of the various medical specialists and/or specialties, including, but not limited to internists, orthopedists, opthamologists, cardiologists, hematologists, endocrinologists, oncologists, ears, nose and throat specialists, neurologists, urologists, gastrointerologists, dermatologists, pediatricians), medical specialist, surgeon, surgical specialists, including any and/or forms and/or types

of surgeons), physician, dentist, psychiatrist, psychologist, optometrist, podiatrist, osteopath, chiropractor, pharmacist, therapist, physical therapist, respiratory therapist, nurse, healthcare aid, nutritionist, and/or any other person, individual and/or professional who can provide healthcare, healthcare relate, wellness and/or wellness-related services and/or products.

As used herein, the terms "insurer", "payer", "insurance provider", "heath insurance provider", "life insurance provider", "disability insuraoce provider", etc., or their plural forms, refers to any insuraoce companies, healthcare insurance companies, disability insurance companies, casualty insurance companies, health maintenance organizations, healthcare providers, and any other payer and/or provider of healthcare services and/or products, who which provide and/or pay for healthcare and/or healthcare-related benefits, services, and/or products, and/or who or which provide respective health insurance, life insurance and/or disability insurance benefits, services and/or products.

As used herein, the terms "broker", "agent", "billing service", "collection agent", "manager", intermediary", "assistant", etc., or their plural forms, refer to any broker, insurance broker, agent, insurance agent, intermediary, third party, billing service provider, collection agent, claim processing agent, and/or any other person, individual, and/or entity, which acts on behalf of, or for, any of the individuals, patients, doctors, healthcare providers, insurers, payers, etc., described herein.

FIG. 1 illustrates the apparatus of the present invention, in block diagram form. The apparatus of the present invention is denoted generally by the reference numeral **100**. In the preferred embodiment, the apparatus **100** of the present invention includes a central processing computer or central processing computer system **10** (hereinafter referred to as the "central processing computer **10**"). In the preferred embodiment the central processing computer can be a network or server computer.

In the preferred embodiment, the central processing computer can provide control over the apparatus **100** and can perform any of the various processing services and/or functions described herein. The central processing computer **10** may be a single computer or system of computers and/or may be include a plurality of computers or computer systems which are utilized in conjunction with one another. The central processing computer **10**, in the preferred embodiment can provides services for any of the other computers and/or computer systems described herein as being associated with any of the individuals, patients, healthcare providers, insurers, payers, brokers, agents, and/or intermediaries, described herein.

The apparatus **100** also includes a healthcare provider communication device or computer **20** (hereinafter referred to as "provider communication device **20**") which is associated with a healthcare provider such as a healthcare professional, a hospital, a clinic, and/or any other provider of services described herein. Any number or amount of healthcare provider computers **20** can be utilized in conjunctioo with a healthcare provider and/or group of providers. The healthcare provider computer(s) **20** can communicate with, and operate in conjunction with, the central processing computer **10** and/or any of the other computers and/or computer systems associated with any of the other individuals and/or entities which utilize and/or operate in conjunction with the present invention.

The apparatus **1** also includes a healthcare payer communication device or computer **30** (hereinafter referred to as "payer communication device **30**") which is associated with a healthcare payer such as a healthcare insurer, insurance company, health maintenance organization, a clinic, and/or any other payer of healthcare services and products described herein. Any number or amount of healthcare payer computers **30** can be utilized in conjunction with a healthcare payer and/or group of payers. The healthcare payer computer(s) **30** can communicate with, and operate in conjunction with, central processing computer **1** and/or any of the other computers and/or computer systems associated with any of the other individuals and/or entities which utilize and/or operate in conjunction with the present invention.

The apparatus **100** also includes a patient or individual user communication device or computer **40** (hereinafter "patient computer **40**") which is associated with a healthcare patient such as a patient, user, or client who seeks or who is provided with healthcare and/or related services, products and/or related information. The patient communication device **40** can also be utilized by any individual, party, or entity, who or which may merely utilize the present invention in order to obtain information of interest.

A patient communication device **40** may also be located at public places or locations, such as at kiosks or other publicly available computer or communication devices. Any number or amount of patient computers **40** can be utilized in conjunction with a patient and/or group of patients. The patient computer(s) **40** can communicate with, and operate in conjunction with, the central processing computer **10** and/or any of the other computers and/or computer systems associated with any of the other individuals and/or entities which utilize and/or operate in conjunction with the present invention.

The apparatus **1** also includes an intermediary communication device or computer **50** (hereinafter referred to as "intmediary computer **50**") which is associated with an intermediary, a broker, an agent, and/or any other individual and/or entity, that can utilize the present invention in order to act for and/or on behalf of any other individual, party, or entity, described herein. Any number or amount of intermediary computers **50** can be utilized in coojunction with an intermediary and/or group of intermediaries. The intermediary computer(s) **50** can communicate with, and operate in conjunction with, the central processing computer **10** and any of the other computers and/or computer systems associated with any of the other individuals and/or eotities which utilize and/or operate in conjunction with the present invention.

In the preferred embodiment, any of the provider computer(s) **20**, the payer computer(s) **30**, the patient computer(s) **40**, and/or the intermediary computer(s) **50**, can be any computer or communication device, including, but not limited to, a personal computer, a home computer, a server computer, a network computer, a hand-held computer, a palmtop computer, a laptop computer, a personal communication device, a personal digital assistant, a telephone, a digital telephone, a television, an interactive televisioo, a beeper, a pager, and/or a watch.

Each of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computer(s) **30**, the patient computer(s) **40**, and/or the intermediary computer(s) **50**, can transmit information to, as well as receive information from, any of the computers **10**, **20**, **30**, **40**, and **50**, described herein. In this regard, each of the computers **10**, **20**, **30**, **40**, and **50**, can communicate with, process information from, and/or share data and/or information with, each other and/or any other computer or computers **10**, **20**, **30**, **40**, and **50**,

described herein and/or utilized in conjunction with the present invention. In this manner, data and/or information transfer between any of the computers **10**, **20**, **30**, **40**, and **50**, can communicate with any other computer or computers **10**, **20**, **30**, **40**, and **50**, in a bi-directional manner.

The central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer(s) **50**, can communicate with one another, and/or be linked to one another, over a communication network, a telecommunication network, a telephone network, a line-connected network, and/or a wireless communication network. Each of the computers **10**, **20**, **30**, **40**, and **50**, can be linked with any other computer or computers directly or indirectly directly or indirectly with one another so as to facilitate a direct or indirect bidirectional communication said respective computers.

In the preferred embodiment, the present invention is utilized on, and/or over, the Internet and/or the World Wide Web. The present invention, in the preferred embodiment, can also utilize wireless Internet and/or World Wide Web services, equipment and/or devices. The central processing computer(s) **10**, in the preferred embodiment, has a web site or web sites associated therewith.

Although the Internet and/or the World Wide Web is a preferred communication system and/or medium utilized, the present invention, in all of the embodiments described herein, can also be utilized with any appropriate communication network or system including, but not limited to, a communication network or system, a telecommunication network or system, a telephone communication network or system, a cellular communication network or system, a wireless communication network or system, a line or wired communication network or system, a wireless Internet network or system, a wireless World Wide Web network or system, a digital communication network or system, a personal communication network or system, a personal communication services (PCS) network or system, a satellite communication network or system, a broad band communication network or system, a low earth orbiting (LEO) satellite network or system, a public switched telephone network or system, a telephone communication network or system, a radio communication network or system, and/or any other communication network or system, and/or any combination of the above communication networks or systems.

In the preferred embodiment, each of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computer(s) **30**, the patient computer(s) **40**, and intermediary computer(s), can transmit data and/or information using TCP/IP, as well as any other Internet and/or World Wide Web, and/or communication, protocols.

The apparatus **100** of the present invention can utilize electronic commerce technologies and security methods, techniques and technologies, in any and/or all of the instances of data and/or information processing, and/or data and/or information transmission described herein.

FIG. **2** illustrates the central processing computer **10**, in block diagram form. The central processing computer **10**, in the preferred embodiment, is a network computer or computer system, or any other communication device which can provide the functionality of, and which can be utilized as a central processing computer such as an Internet server computer and/or a web site server computer. In the preferred embodiment, the central processing computer **10** includes a central processing unit or CPU **10A**, which in the preferred embodiment, is a microprocessor. The CPU **10A** may also be a microcomputer, a minicomputer, a macro-computer, and/or a mainframe computer, depending upon the application.

The central processing computer **10** also includes a random access memory device(s) **10B** (RAM) and a read only memory device(s) **10C** (ROM), each of which is connected to the CPU **10A**, a user input device **10D**, for entering data and/or commands into the central processing computer **10**, which includes any one or more of a keyboard, a scanner, a user pointing device, such as, for example, a mouse, a touch pad, and/or an audio input device and/or a video input device, and/or any device, electronic and/or otherwise which can be utilized for inputting and/or entering healthcare data and/or information, for example pulse rate monitors, blood pressure monitors, electrocardiograms, blood-sugars monitors, etc., if desired, which input device(s) are also connected to the CPU **10A**. The central processing computer **10** also includes a display device **10E** for displaying data and/or information to a user or operator.

The central processing computer **10** also includes a transmitter(s) **10F**, for transmitting signals and/or data and/or information to any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer(s) **50** individual computer(s), which may be utilized in conjunction with the present invention. The central processing computer **10** also includes a receiver **10G**, for receiving signals and/or data and/or information from any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer(s) **50**, which may be utilized in conjunction with the present invention.

The central processing computer **10** also includes a database(s) **10H** which contains data and/or information pertaining to the patients, providers, payers, and intermediaries who or which are serviced by the present invention and/or who or which utilize the present invention.

The database **10H** contains any and/or all of the information needed and/or required in order to perform any and/or all of the functions, services and/or operations described herein as being performed by the central processing computer **10** or the apparatus **100** of the present invention. In this regard the database **10H** contains data and/or information regarding patient name, patient identification information, patient social security number or other identification information, date of birth, doctors or providers, therapists, nutritionists, insurance or payer information, group insurance information, group health insurance information, life insurance information, disability insurance information, patient address, phone number, e-mail and/or other contact information, medical history, psychological history, dental history, family history, family medical, psychological, and/or dental history, insurance coverage, insurance co-payment and/or deductible information, insurance information, insurance claim procedures, insurance claim forms, doctor or provider appointment schedules, past treatments, past diagnosis, symptoms, insurance claim forms, employer information, lifestyle information, treatment plans, treatment progress, broker/agent/intermediary information, education information, age, sex, marital status, employee benefits information, types or services and/or treatments needed, and any other data and/or information regarding the patient which would be needed and/or desired in order to perform any and/or all of the functions, services and/or operations described herein.

The database(s) **10H** can also contain healthcare and/or medical video, image, and/or audio, data and/or information,

such as, for example, x-rays, Magnetic Resonant Images (MRI), CAT scans, digital x-ray files, digital Magnetic Resonant Imaging (MRI) files, digital CAT scan files, and/or any other video, imaging, and/or audio, healthcare data and/or information which can be utilized by healthcare providers, payers, intermediaries, patients, and/or other users of the present invention. In this manner, the present invention can facilitate the availability of any of the above-described video, image, and/or audio, data and/or information in a network environment. For example, a medical specialist can have access to, and/or review, an MRI or a CAT scan for a patient, from any location and at any time.

The database **10**H also data and/or information regarding providers including provider name, provider social security number or identification number, type of professional or service provider, address, phone number, fax number, e-mail and/or other contact information, experience, specialities, insurances accepted, schedule of charges, financial account identification information, resume information, education, work experience, claim forms, appointment schedules, procedures performed, and/or any other data and/or information concerning the providers for providing any and/or all of the functions, services, and/or operations described herein as being performed by the present invention.

The database **10**H also includes data and/or information regarding all possible fields of medicine, surgery, psychiatry, psychology, dentistry, oral surgery, optometry, podiatry, physical therapy, respiratory therapy, hypnosis, osteopathy, nutrition, wellness, and/or any other possible healthcare fields and/or subject matter which can possibly by utilized in the processing and/or operation of the present invention. The database **10**H contains information on illnesses, symptoms, diseases and/or sicknesses, theories, scientific theories, research data and/or information, diagnosis information, treatment information, treatment plans, treatment processes, treatment progresses, treatment interactions, side effects, expected treatment results, treatment providers, treatment durations, treatment costs, pre-treatment information, post-treatment information, treatment monitoring information, statistical information regarding diagnoses, treatments, treatment success rates, treatment failure rates, treatment centers, therapy plans, therapy success rates, therapy failure rates, treatment procedures, medications treatments, non-medication treatments, healthcare institutions, treatment evaluating criteria, treatment mistakes and/or mishaps, indicators of mistakes and/or mishaps, corrective actions, links to providers, links to treatment centers or institutions, reimbursement rates, nutrition information, diet information, exercise information, exercise routines, treatment options, healthcare advise, wellness advice, preventive care, preventive procedure, health maintenance, drug and medication information, drug interaction information, video information, including video files or clips and other information, regarding illnesses, diseases, treatments and follow-up care, audio information, including audio files or clips and other information, regarding illnesses, diseases, treatments and follow-up care, treatment and/or procedure information and/or narratives, treatment analysis, diagnosis analysis, diagnosis monitoring, diagnosis confirmation and/or checking, and/or other information for providing the herein-described functions, services, and/or operations.

The database **10**H also contains information regarding The insurance companies and payers described herein, including, but not limited to, payer name, address, phone number, fax number, e-mail address, identification number (s), coverage types, policies and/or coverages provided, reimbursement rates, patients and/or providers serviced and/or covered by the payer, policy information, claim forms, claim procedures, claim status, claim processing information, claim submission procedures and policies, reasonable and customary charges, co-payment information, pre-approval information and/or procedures, claim form information, electronic form claim forms, insurance and/or coverage requirements, guidelines, and/or triggering events, covered procedures and/or treatments, uncovered procedures and/or treatments, claim approval information, claim approval history, claim approval statistics, claim rejection or denial information, claim rejection or denial history, claim rejection or denial statistics, financial account information, network provider information, network patient information, claim statistics, preventative care and/or benefits information, benefits information, benefits request information and/or claim forms, claim submission information, claim processing information, claim status information, payment information and statistics, and/or any other data and/or information regarding and/or related to payers which are needed and/or desired for providing any and/or all of the functions, services, and/or operations described herein.

The database **10**H also contains data and/or information regarding the brokers, agents and/or intermediaries described herein, including, but not limited to, intermediary name, address, phone number, fax number, e-mail address, clients, patients services, insurance policies, policy information, policy quote information, policy proposal information, any and/or all of the above information described herein regarding patients, providers, payers, etc. which may be of interest to the intermediaries described herein which may be useful and/or beneficial to the intermediaries in providing any of the functions, services, and/or operation described herein.

The database **10**H also includes contact information such as phone numbers, fax numbers, pager numbers, beeper numbers, e-mail addresses, hyperlinks to, and/or any other information which can facilitate contact between any of the parties described herein. The database **10**H also includes electronic signature data and/or information for any of the parties, patients, providers, payers, and/or intermediaries, described herein for facilitating transactions, claim submissions, financial transactions, etc., by and/or between any of the above patients, providers, payers, and/or intermediaries.

The data and/or information in the database **10**H can also include links to any other information, information sources, news sources, and/or other information and/or data which can or may be utilized by the present invention and/or by any of the patients, providers, payers, intermediaries and/or any other users of the present invention.

The database **10**H also contains data and/or information regarding healthcare news, healthcare developments, healthcare discoveries, etc., for and including the medical field, surgical field, psychological field, dental field, nutrition field, fitness field, etc., and/or any other healthcare field or fields. The database **10**H, in the preferred embodiment, also contains video and/or audio files which can be utilized for training of healthcare professionals as well as for providing general information to any user of the present invention. In this manner, and as will be described hereinbelow, the apparatus **100** can be utilized as a simulator for providing training in medical diagnosing, medical training, surgical training, psychiatric training, psychological training, dental training, oral surgery training, therapist training, and/or for training any of the healthcare providers described herein and/or envisioned.

For example, the present invention can be utilized to provide a medical doctor with a set of symptoms, evaluate

the diagnosis and treatment prescribed and provide follow-up patient conditions which may or may not call for the medical doctor to re-evaluate his or her diagnosis and/or treatment. In a similar fashion, the present invention can he used for training and continuing education and training for any of the healthcare providers described herein and/or otherwise envisioned utilizing the present invention.

The database **10**H can also contain data and/or information restricting access by any of the providers, payers, patients, intermediaries, and/or other users, to any of the data and/or information stored in the database **10**H.

The database **10**H also contains information correlating symptoms and/or conditions with diagnoses, prognoses, and/or treatments, treatment methods, procedures, etc. The database **10**H also contains any and/or all information needed and/or desired for facilitating the processing of symptoms, conditions, medical histories, family histories, and other information, in order to arrive at diagnoses and/or prognoses, treatments, prescriptions, procedures and/or any other healthcare and/or healthcare-related information.

The database **10**H also contains statistical and/or other probabilistic and/or mathematical information for assigning and/or correlating certain levels and/or estimates for any and/or all of the information, diagnoses, prognoses, treatments, procedures, and/or any other information processed and/or generated by the central processing computer **10** and/or the apparatus **100**. Applicant hereby incorporates by reference herein the teachings of *Basic Business Statistics Concepts and Applications*, Mark L. Berenson and David M. Levine, 6th Edition, Prentice Hall 1996.

The database **10**H, in the preferred embodiment, can be a database which may include individual databases or collections of databases, with each database being designated to store any and all of the data and/or information described herein. The database **10**H, or collection of databases, may be updated by each of the respective patients, providers, payers, users, and/or intermediaries, arid/or by any other third party, in real-time, and/or via dynamically linked database management techniques.

The data and/or information stored in the database **10**H can also be updated by and/or dyamically linked to, various external sources, including but not limited to news services, research publications, research facilities, healthcare laboratories, providers of healthcare goods and/or services, pharmaceutical companies, research institutions, schools. The database **10**H will contain any and all information deemed necessary and/or desirable for providing all of the processing and/or services and/or functions described herein. Applicant hereby incorporates by reference herein the subject matter of *Fundamentals of Database Systems*, by Ramez Elmasri and Shamkant B. Navathe, 2nd Ed., Addison-Wesley Publishing Company, 1994.

The data and/or information which is contained and/or stored in the database **10**, as well as any of the other databases **20**H, **30**H, **40**, and **50**H, described herein can be obtained from the various patients, individuals, providers, payers, and/or intermediaries, who or which utilize and/or who or which are serviced by the present invention. For example, the respective patients, providers, payers, intermediaries, and/or other users, could fill out questionnaires, forms, narratives, claim forms, and/or any other information medium, in written form, electronically, and/or otherwise.

Data and/or information stored in the database **10**H as well as any of the other databases described herein can be updated by multiple parties. For example, a patient may provided medical history for his or her individual file, his or her medical doctor can update the medical history information for the patient upon examining and/or treating him or her. The payer may also update the file with any associated payment or payment-related information. Should the patient go to another doctor or different type of doctor, all previous information would be available for, and can be updateable by, the next doctor.

The database **10**H can also contain information regarding alternate medicine techniques, herbal techniques, meditation techniques, exercise techniques, self healing, faith healing, and/or other non-medicine treatments and/or techniques.

The database **10**H can also include statistical data and/or information regarding diagnoses, and/or alternate diagnoses, treatment success, treatment failure, as well as statistical data and/or information regarding misdiagnoses. The database **10**H also contains data and/or information regarding experimental treatments as well as statistical information regarding same, successes of same and failures of same.

In any and/or all of the embodiments described herein, any of the data and/or information which is or which may be stored in the database **10**H, and/or any of the other databases described herein, can be utilized and/or can appear in any of the reports, diagnostic reports, treatment reports, evaluation reports, provider reports, payer reports, patient reports, training reports, and/or any other reports, described herein.

The central processing computer **10** also includes an output device **10**I for output any data, information, report, etc., described herein. In the preferred embodiment, the output device **10**I can be a printer, a display, a transmitter, a modem, and/or any other device which can be used to output data.

Any of the data and/or information for any of the patients, individuals, providers, payers, and/or intermediaries, can be updated by different parities and which such updated data and/or information being made available to other respective parties so as to provide and ensure comprehensive and up-to-date healthcare and healthcare-related information.

FIG. **3** illustrates the provider communication device **20**, in block diagram form. The provider communication device **20**, in the preferred embodiment, can be personal computer, a network computer or computer system, or any other computer or communication device, which is utilized as a provider computer. In the preferred embodiment, the provider communication device **20** includes a central processing unit or CPU **20**A, which in the preferred embodiment, is a microprocessor. The CPU **20**A may also be a microcomputer, a minicomputer, a macro-computer, and/or a mainframe computer, depending upon the application.

The provider communication device **20** also includes a random access memory device(s) **20**B (RAM) and a read only memory device(s) **20**C (ROM), each of which is connected to the CPU **20**A, a user input device **20**D, for entering data and/or commands into the provider communication device **20**, which includes any one or more of a keyboard, a scanner, a user pointing device, such as, for example, a mouse, a touch pad, and/or an audio input device and/or a video input device, and/or any device, electronic and/or otherwise which can be utilized for inputting and/or entering healthcare data and/or information, for example pulse rate monitors, blood pressure monitors, electrocardiograms, blood-sugars monitors, etc., if desired, which input device(s) are also connected to the CPU **20**A. The provider communication device **20** also includes a display device **20**E for displaying data and/or information to a user or operator.

The provider communication device **20** also includes a transmitter(s) **20**F, for transmitting signals and/or data and/or information to any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer(s) **50** individual computer(s), which may be utilized in conjunction with the present invention. The provider communication device **20** also includes a receiver **20**G, for receiving signals and/or data and/or information from any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer (s) **50**, which may be utilized in conjunction with the present invention.

The provider communication device **20** also includes a database(s) **20**H. The database **20**H can contain and/or be linked to any of the data and/or information described herein as being stored in the database **10**H.

The provider communication device **20** also includes an output device **20**I for output any data, information, report, etc., described herein. In the preferred embodiment, the output device **20**I can be a printer, a display, a transmitter, a modem, and/or any other device which can be used to output data.

FIG. **4** illustrates the payer communication device **30**, in block diagram form. The payer communication device **30**, in the preferred embodiment, can be personal computer, a network computer or computer system, or any other computer or communication device, which is utilized as a payer computer. In the preferred embodiment, the payer communication device **30** includes a central processing unit or CPU **30**A, which in the preferred embodiment, is a microprocessor. The CPU **30**A may also be a microcomputer, a minicomputer, a macro-computer, and/or a mainframe computer, depending upon the application.

The payer communication device **30** also includes a random access memory device(s) **30**B (RAM) and a read only memory device(s) **30**C (ROM), each of which is connected to the CPU **30**A, a user input device **30**D, for entering data and/or commands into the payer communication device **30**, which includes any one or more of a keyboard, a scanner, a user pointing device, such as, for example, a mouse, a touch pad, and/or an audio input device and/or a video input device, and/or any device, electronic and/or otherwise which can be utilized for inputting and/or entering healthcare data and/or information, for example pulse rate monitors, blood pressure monitors, electrocardiograms, blood-sugars monitors, etc., if desired, which input device(s) are also connected to the CPU **30**A. The payer communication device **30** also includes a display device **30**E for displaying data and/or information to a user or operator.

The payer communication device **30** also includes a transmitter(s) **30**F, for transmitting signals and/or data and/or information to any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer(s) **50** individual computer(s), which may be utilized in conjunction with the present invention. The payer communication device **30** also includes a receiver **30**G, for receiving signals and/or data and/or information from any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer (s) **50**, which may be utilized in conjunction with the present invention.

The payer communication device **30** also includes a database(s) **30**H. The database **30**H can contain and/or be linked to any of the data and/or information described herein as being stored in the database **10**H.

The payer communication device **30** also includes an output device **30**I for output any data, information, report, etc., described herein. In the preferred embodiment, the output device **30**I can be a printer, a display, a transmitter, a modem, and/or any other device which can be used to output data.

FIG. **5** illustrates the patient communication device **40**, in block diagram form. The patient communication device **40**, in the preferred embodiment, can be personal computer, a network computer or computer system, or any other computer or communication device, which is utilized as a patient computer. In the preferred embodiment, the patient communication device **40** includes a central processing unit or CPU **40**A, which in the preferred embodiment, is a microprocessor. The CPU **40**A may also be a microcomputer, a minicomputer, a macro-computer, and/or a mainframe computer, depending upon the application.

The patient communication device **40** also includes a random access memory device(s) **40**B (RAM) and a read only memory device(s) **40**C (ROM), each of which is connected to the CPU **40**A, a user input device **40**D, for entering data and/or commands into the patient communication device **40**, which includes any one or more of a keyboard, a scanner, a user pointing device, such as, for example, a mouse, a touch pad, and/or an audio input device and/or a video input device, and/or any device, electronic and/or otherwise which can be utilized for inputting and/or entering healthcare data and/or information, for example pulse rate monitors, blood pressure monitors, electrocardiograms, blood-sugars monitors, etc., if desired, which input device(s) are also connected to the CPU **40**A. The patient communication device **20** also includes a display device **40**E for displaying data and/or information to a user or operator.

The patient communication device **40** also includes a transmitter(s) **40**F, for transmitting signals and/or data and/or information to any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer(s) **50** individual computer(s), which may be utilized in conjunction with the present invention. The patient communication device **40** also includes a receiver **40**G, for receiving signals and/or data and/or information from any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer(s) **50**, which may be utilized in conjunction with the present invention.

The patient communication device **40** also includes a database(s) **40**H. The database **40**H can contain and/or be linked to any of the data and/or information described herein as being stored in the database **10**H.

The patient communication device **40** also includes an output device **40**I for output any data, information, report, etc., described herein. In the preferred embodiment, the output device **40**I can be a printer, a display, a transmitter, a modem, and/or any other device which can be used to output data.

FIG. **6** illustrates the intermediary computer **50**, in block diagram form. The intermediary computer **50**, in the preferred embodiment, can be personal computer, a network computer or computer system, or any other computer or

communication device, which is utilized as an intermediary computer provider. In the preferred embodiment, the intermediary computer **50** includes a central processing unit or CPU **50**A, which in the preferred embodiment, is a microprocessor. The CPU **50**A may also be a microcomputer, a minicomputer, a macro-computer, and/or a mainframe computer, depending upon the application.

The intermediary computer **50** also includes a random access memory device(s) **50**B (RAM) and a read only memory device(s) **50**C (ROM), each of which is connected to the CPU **50**A, a user input device **50**D, for entering data and/or commands into the intermediary computer **50**, which includes any one or more of a keyboard, a scanner, a user pointing device, such as, for example, a mouse, a touch pad, and/or an audio input device and/or a video input device, and/or any device, electronic and/or otherwise which can be utilized for inputting and/or entering healthcare data and/or information, for example pulse rate monitors, blood pressure monitors, electrocardiograms, blood-sugars monitors, etc., if desired, which input device(s) are also connected to the CPU **50**A. The intermediary computer **50** also includes a display device **50**E for displaying data and/or information to a user or operator.

The intermediary computer **50** also includes a transmitter (s) **50**F, for transmitting signals and/or data and/or information to any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer (s) **50** individual computer(s), which may be utilized in conjunction with the present invention. The intermediary computer **50** also includes a receiver **50**G, for receiving signals and/or data and/or information from any one or more of the central processing computer(s) **10**, the provider computer(s) **20**, the payer computers(s) **30**, the patient computer(s) **40**, and the intermediary computer(s) **50**, which may be utilized in conjunction with the present invention.

The provider communication device **50** also includes a database(s) **50**H. The database **50**H can contain and/or be linked to any of the data and/or information described herein as being stored in the database **10**H.

The intermediary communication device **50** also includes an output device **50**I for output any data, information, report, etc., described herein. In the preferred embodiment, the output device **50**I can be a printer, a display, a transmitter, a modem, and/or any other device which can be used to output data.

In any and/or all of the embodiments described herein, any one of the central processing computers **10**, the provider communication devices **20**, the payer communication devices **30**, the patient communication devices **40**, and/or the intermediary communication devices **50**, can include input devices (not shown) for facilitating the data entry of a patients vital signs and or other medical data such as, but not limited to, pulse rate, blood pressure, blood-sugar level, etc., and any other data and or information which can be input into the respective computer and/or communication device and be transmitted to the central processing computer consistent with the utilization of the present invention as described herein.

The apparatus and method of the present invention can be utilized in numerous preferred embodiments in order to provide a vast array of healthcare and healthcare-related services for any one or more of the various parties described herein. While certain of the preferred embodiments may be described with regards to utilization by a particular party, it is important to note that any patient, user, provider, payer, and/or intermediary may utilize the present invention in the same, similar and/or analogous manner. For example, a preferred embodiment for determining and/or ascertaining a medical diagnosis can be described as being utilized by a treating physician as well as be utilized by a provider to verify and/or check a diagnosis as well as by a patient or other user or individual in order to perform a self-diagnosis or double check a doctors diagnosis. In the same manner, any other preferred embodiment and/or other uses of the present invention can be utilized by any of the parties described herein.

The present invention, in its various preferred embodiments can be utilized to create and maintain comprehensive patient databases which can be accessed via a network environment and/or otherwise, to perform healthcare and/or healthcare-related diagnoses, to provide healthcare and/or healthcare-related expected prognoses, to provide healthcare and/or healthcare-related treatment plans or programs, and/or to provide healthcare and/or healthcare-related treatment progress reports and/or evaluations.

The present invention can also be utilized in order to provide training and continuing education services for healthcare and/or healthcare-related professionals, to provide healthcare, healthcare-related, and/or wellness information, to provide information about healthcare and/or healthcare-related patient, providers, payers, and/or intermediaries, to provide scheduling management services for providers, to provide notification services for patients, providers, payers and/or intermediaries and/or any other parties described herein, and/or to locate providers, payers and/or intermediaries.

The present invention can also be utilized, in preferred embodiments, in order to healthcare and/or healthcare-related claim processing services, claims submissions, claim processing, claim status checking, and claim reconciliation, claim fraud prevention, treatment evaluation, healthcare and/or healthcare insurance policy generation, management and administration, provider, payer and/or intermediary evaluation, drug and/or treatment interactivity, treatment, medication and/or organ availability and/or notification services, patient, provider, payer, intermediary, and/or third party, notification services.

The present invention can also be utilized as a clearing-house for facilitating the offering, selling, buying, trading, and/or other commerce and/or transactions, involving healthcare and/or healthcare-related services, products and/or goods.

In any and/or all of the embodiments described herein, the various computers and/or communication devices **10**, **20**, **30**, **40** and/or **50**, can be utilized to transmit and/or to receive transmissions, information, messages, and/or notification messages and/or signals to, and/or between, the respective parties associated with the respective computers and/or communication devices. The transmission of information, messages, and/or notification messages and/or signals, in any and/or all of the embodiments described herein can be effected via any one or more of e-mail messages, telephone messages, beeper or pager messages, physical mail delivery, electronic data transmission, and/or can be made via any other suitable and/or appropriate communication method and/or technique.

In a preferred embodiment, the present invention can be utilized in order to perform a diagnosis of a sickness, illness and/or other condition. FIGS. **7**A and **7**B illustrate a preferred embodiment method of using the present invention, in block diagram form. While the method of FIGS. **7**A and **7**B

is described in the context of a medical doctor performing a diagnosis of a medical condition, the method of FIGS. 7A and 7B can be similarly utilized by surgeons, psychologists, psychiatrists, dentists, and/or any other healthcare provider or healthcare professional described herein. The method of FIGS. 7A and 7B may also be utilized by any user, patient, provider, payer, and/or intermediary in order to ascertain a diagnosis and/or in order to check on, verify, and/or ascertain the correctness of a diagnosis of another.

The operation of the apparatus **100** commences at step **700**. At step **701**, the provider will access the central processing computer **10** and enter data and/or information regarding the patient. At step **702**, the central processing computer **10** will determine if a file and/or medical history exists for the patient. If, at step **702**, it is determined that a medical history does not exist, the central processing computer **10** will, at step **703**, request that a medical history, family history and/or other information related thereto be provided by the patient or accompanying individual. At step **703**, the information obtained by the patient or accompanying individual will then be entered via the provider communication device **20** and transmitted to, and be stored at, the central processing computer **10**. Thereafter, processing will proceed to step **704**.

If, at step **702**, it is determined that a patient's medical history does in fact exist, the processing will proceed to step **704**. At step **704**, the patient's symptoms, if any, and/or examination findings, are obtained from the patient and transmitted from the provider communication device **20** to the central processing computer **10**. The central processing computer **10** will, at step **705** receive and process the patient symptoms, if any, and/or examination findings, in conjunction with the patient's medical history and/or other information, medical theories, principles, criteria and/or other medical information needed to make a diagnosis. At step **705**, the central processing computer **10** will perform a comprehensive diagnostic evaluation of the patient's symptoms, if any, and/or the examination findings.

At step **706**, the central processing computer will generate a diagnostic report which can include a diagnosis of the patient's condition, if needed. The diagnostic report which is generated at step **706** can, if needed, include a single diagnosis and/or a list of possible diagnoses, along with their respective probabilities of occurrence and/or statistical information corresponding thereto, which may pertain to the patient's condition. At step **707**, the central processing computer **10** will then generate a treatment report which will outline and/or prescribe treatment for the single diagnosis and/or for the list of possible diagnoses, if any. The central processing computer **10**, when generating the treatment report, can process same in conjunction with, and consider, possible drug interactions and/or treatment interactions.

At step **708**, the central processing computer **10** will transmit the diagnostic report and/or treatment report to the provider's communication device **20** at which point the medical doctor can obtain the diagnosis or possible diagnoses, if any, and corresponding treatment plans. The medical doctor can then, at step **709**, review the diagnostic report and/or treatment report and choose the a final diagnosis and/or treatment plan, if needed, to administer to the patient.

At step **710**, the medical doctor will transmit the final diagnosis and treatment plan, including the prescribed treatment and/or treatment plan, if any, to the central processing computer **10**. At step **711**, the central processing computer **10** will then update the patient's records in the database **10**H so as to include all of the data and information described as being processed and/or generated by the central processing computer **10**, including, but not limited to the patient's symptoms, if any, the examination findings, the information contained in the diagnostic report and the treatment report, the final diagnosis and the prescribed treatment.

Thereafter, operation of the apparatus **100** will cease at step **712**. The patient's records will then be updated and be available for the patient's next treatment and/or diagnosis.

In another preferred embodiment, the diagnostic report and/or treatment reports can be accompanied by medical information, textbook materials, laboratory materials, reference materials, video clips of any pertinent information, audio clips of any pertinent information, hyperlinks to informational sources, information regarding providers and/or facilities for obtaining treatment and/or therapy, provider and/or facility contact information, and/or any other pertinent and/or relevant information.

In another preferred embodiment, the diagnostic report and/or treatment reports can be accompanied by health and/or wellness information which can include suggestions for health and/or wellness foods, goods, products, and/or services. The diagnostic report and/or treatment reports can also be accompanied by health and/or fitness information, diets, nutritional information, and/or any other information which may be of assistance to the patient and/or provider. The diagnostic and/or treatment reports can also contain warnings regarding misdiagnoses, warnings about treatments, information about experimental treatments, etc. The diagnostic and/or treatment reports can also contain information, statistical and/or otherwise, regarding diagnoses, misdiagnoses, treatment successes, and/or treatment failures. The diagnostic and/or treatment reports can also contain information regarding alternate medicine such as treatments regarding herbal remedies and/or treatments, meditation, self-healing, faith healing, yoga, tai chi, exercise therapy, and/or other therapies and/or therapy types.

As noted above, the method of utilizing the present invention, as described in FIGS. 7A and 7B, is equally applicable to, and can be utilized in the same manner, by any and/or all of the respective healthcare providers, professionals, and/or related providers.

In another preferred embodiment, the apparatus and method of the present invention can be utilized to ensure that a proper treatment and/or procedure is performed on the patient. Referring once again to FIGS. 7A and 7B and the above description of same, the present invention can be utilized to ensure that a subsequent treatment and/or treatments are performed as prescribed. As noted above with reference to FIG. **6** and, in particular, a final diagnosis and prescribed treatment is stored in the patient's file or records in the database **10**H of the central processing computer. When the patient seeks treatment from a subsequent medical doctor, surgeon, or other healthcare professional, the medical doctor, surgeon, or other healthcare professional, can access the central processing computer **10** at the time of treatment, access the patient's medical history and prescribed treatment plan and assess same in order to make sure that the treatment to be provided is called for in the prescribed treatment. In this manner, the present invention can be utilized in order to prevent medical and/or surgical mistakes, mishaps and/or other instances when improper treatment could occur. It is also envisioned that the subsequent care medical doctor, surgeon, or other healthcare professional, could also re-evaluate the patient's condition and/or records and seek additional assistance and/or perform

a separate and independent assessment and/or diagnosis of the patient. In any event, the present invention can provide the subsequent care medical doctor, surgeon, or other healthcare professional, with the patient's complete medical history, information, past diagnoses and/or past treatments and/or prescriptions. In this manner, a subsequent care provider can be provided with as complete and as up to date information as possible in order to administer treatment.

For example, the present invention can be utilized in the following manner. A patient scheduled for surgery on a certain body part (i.e. left ankle) may enter the hospital. Due to a hospital clerical error, the right ankle is noted to be operated on. Prior to the surgery, the surgeon may access the central processing computer **10**, via a provider communication device **20** located in the operating room, and/or another location in the hospital, in order to verify the procedure to be performed. In response thereto, the central processing computer **10** will transmit a message that it is the left ankle which is to be operated on. Thereafter, the surgeon can investigate the situation and ensure that the correct and prescribed surgery and/or procedure is performed. Once the surgery is completed, the patient's record will be updated accordingly. While a surgical procedure is described, it is important to note that any treatment, procedure, etc., which can be performed by any healthcare professional described herein, and/or in any healthcare field described herein, can be verified in the above-described manner. In this manner, the present invention can be utilized to pre-screen subsequent and/or follow-up treatments and/or procedures so as to prevent healthcare mistakes and/or mishaps.

In another preferred embodiment, the healthcare professional can access the central processing computer **10** via the provider communication device **20**, access the patient's or client's record and input information concerning the treatment and/or procedure to be performed. Thereafter, the central processing computer **10** can process the information and transmit a message to the healthcare professional notifying the healthcare professional that the treatment and/or procedure is either the prescribed treatment or procedure or that it is not the prescribed treatment and/or procedure. The message provided by the central processing computer, to the treating healthcare professional, can also include information regarding the treatment and/or the procedure, such as instructions, steps, and/or any other accompanying information.

In any and/or all of the embodiments described herein, the central processing computer **10**, in performing any processing of patient information, diagnosis information, and/or treatment information, described herein, can perform such processing in conjunction with drug and/or other treatment interaction information so as to provide an added safeguard in the diagnosis and treatment planning processes. Any and/or all processing described herein is also performed in conjunction with each patient's medical history, family history, allergic conditions information, and/or with any other information deemed important and/or essential in the an individual's healthcare diagnoses and/or treatments.

In another preferred embodiment, the present invention can be utilized to perform treatment evaluations and/or treatment monitoring. In this manner, the present invention can be utilized by any of the providers, payers, patients, users, and/or intermediaries, described herein to evaluate and/or monitor treatments, provide training and/or oversight for healthcare providers and/or professionals, and/or allow payer and/or insurance companies to evaluate treatments, treatment plans, treatment progress, and/or any other evaluations and/or verifications for healthcare claims processing. In this embodiment, the present invention can be utilized so as to safeguard against the use of incorrect and/or unconventional and/or fraudulent treatment and/or care.

FIGS. **8**A and **8**B illustrate another preferred embodiment of a method of use of the present invention, in flow diagram form. FIGS. **8**A and **8**B illustrate a preferred embodiment method of use of the present invention in order to evaluate and/or monitor treatments, treatment plans and/or the administration of healthcare. While described as being utilized by payers and/or an insurance company in evaluating and/or monitoring treatment, it is important to note that the embodiment of FIGS. **8**A and **8**B can be utilized by any provider, patient, user, including healthcare students and/or healthcare professionals-in-training, or other providers, and/or intermediary, for obtaining the information provided by the embodiment of FIGS. **8**A and **8**B and utilizing it any manner they see fit.

With reference to FIGS. **8**A and **8**B, the operation of the apparatus **100** commences at step **800**. At step **801**, the payer or payer's employee or agent (hereinafter, for simplicity, referred to at payer's employee) can access the central processing computer **10**. At step the payer's employee can enter information concerning the patient, the treatment, and/or care, which is desired to be evaluated and/or monitored. At step **802**, the central processing computer **10** will access the database **10**H and obtain patient information, patient medical history, family history, if pertinent, symptom information, provider information, diagnostic report information, treatment report information, final diagnoses information, prescribed treatment information, and/or any other information which can be relevant and/or pertinent. Any and/or all of the information described above can be stored in the database **10**H from prior processing and/or use of the present invention. Other data and/or information can also be obtained from the payer's employee and/or from other third party and/or outside sources.

At step **803**, the central processing computer **10** will perform a processing routine in conjunction with the above-described information in order to determine if the diagnoses and associated and/or related treatment or treatments are appropriate and/or in-line with current standards for the given healthcare field. The central processing computer **10** can also calculate and/or provide statistical information regarding any of diagnoses and/or treatments under study. At step **804**, the central processing computer **10** will generate an evaluation report which will provide data and information regarding the information obtained from step **803**.

The central processing computer **10** can then, at step **805**, transmit the evaluation report and/or any other appropriate information, to the payer communication device **30**. The central processing computer, in another preferred embodiment, can, at step **803** and/or at. step **804**, determine and/or provide, as part of the evaluation report, information concerning whether the diagnoses and/or treatments are considered appropriate and/or valid, and/or in-line with standards, as well as recommend that claims for the treatment(s) are valid and should be paid by the payer, and/or that the claims for the treatment(s) are invalid and should be denied.

Thereafter, at step **806**, the payer or the payer's employee can review the evaluation report and take any action deemed appropriate. At step **807**, the payer or payer's employee can transmit data and/or information regarding the payer's or payer employee's action and/or decision. Step **807** is an optional step and can be dispensed with if the payer or payer's employee chooses not to respond to and/or to

transmit information to, the central processing computer **10**. Thereafter, the operation of the apparatus will cease at step **808**.

The present invention when utilized as described in FIGS. **8**A and **8**B, can provide treatment evaluation and/or monitoring for healthcare payers which can be utilized for performing claims processing, provider evaluations, patient evaluations, and/or any other useful and/or desired purpose. The present invention, when utilized as described in FIGS. **8**A and **8**B, can also be utilized by any provider, patient, payer, user, and/or intermediary, to evaluate and/or monitor treatments, evaluate providers, evaluate patients, evaluate payers, ascertain payers claims paying and/or processing trails, and/or for educational purposes and/or for any other useful and/or desired purpose.

In another preferred embodiment of the present invention, the apparatus and method of the present invention can be utilized to create and maintain a comprehensive patient healthcare database. FIGS. **9**A and **9**B illustrate another preferred embodiment use of the present invention, in flow diagram form. With reference to FIGS. **9**A and **9**B, the operation of the apparatus **100** commences at step **900**. At step **901**, the patient will access the central processing computer **10** and provide identification information. At step **902**, the central processing computer **10** will determine whether the patient has an account and/or a file with the central processing computer and/or the service utilizing same. If, at step **902**, it is determined that the patient does not have an account with the central processing computer **10**, the processing will proceed to step **903** and patient will be prompted and/or asked to fill out any necessary forms and/or answer questions so as to provide a comprehensive medical history and family history, if possible. All provided data and/or information will be stored in the database **10**H and a patient account, file and/or record will be created at step **903**. Thereafter, processing will proceed to step **904**. If, at step **902**, the patient is determined to have an account with the central processing computer, processing will proceed directly to step **904**.

At step **904**, the patient will provide information concerning the present healthcare request and present provider information. At step **905**, the central processing computer **10**, will then determine if the present provider is a new provider. If, at step **905**, it is determined that the present provider is a new provider, the central processing computer **10** will proceed to step **906** and update the patient's files or records so as to include the present provider as a new provider for the patient. Thereafter, the central processing computer **10** will proceed to step **907** and will process and store, in the database **10**H and/or in the patient's files or records, any pertinent patient information, symptoms, diagnoses and/or treatments, final diagnosis and/or prescribed treatment, for the provider visit or for the event or occurrence.

If, however, at step **905**, it is determined that the present provider is an existing provider for the patient, the central processing computer **10** will proceed directly to step **907** and process and store, in the database **10**H and/or in the patient's files or records, any pertinent patient information, symptoms, diagnoses and/or treatments, final diagnosis and/or prescribed treatment, for the provider visit or for the event or occurrence. Thereafter, operation of the present invention will cease at step **908**.

In this manner, the present invention can be utilized so as to create and maintain a comprehensive healthcare patient database which can be accessed by any provider, payer, intermediary, and/or other party or user, in order to access the patient's healthcare files and/or records. The comprehensive database, which in the preferred embodiment of the present invention, is stored and/or maintained in the database **10**H of the central processing computer **10**, can contain and/or store any of the data and/or information obtained from, and/or provided by, any and/or all of the herein-described embodiments of the present invention.

The comprehensive database provides a data and/or information source which can be accessed by any provider, from anywhere in the world, and at any time, in order to obtain information about a patient in his, her, or its care. For example, a patient traveling far from home and out of reach by his or her current healthcare provider can be treated by another provider who can access the central processing computer **10**, from any location, and at any time, and obtain up-to-date and/or comprehensive patient healthcare and/or medical and family history information, current healthcare and/or medical condition, current treatment and/or care and/or any other information which can facilitate optimal healthcare and/or medical treatment.

In the same manner, new providers can obtain existing information concerning healthcare and/or medical history, family history, current healthcare conditions and/or treatments as well as any other information from the central processing computer **10**, Thereby allowing the new provider to obtain accurate information and dispensing with the need to obtain same form the patient. The information provided from the present invention can also assist the provider in diagnosing the patient. Providers can also utilize the comprehensive database in order to ascertain past and/or current providers who may be contacted for assistance and/or for insight in the treatment process.

In a similar manner, payers can utilize the comprehensive database in order to ascertain payer eligibility, the existence of pre-existing conditions and/or to obtain any other useful information.

In another preferred embodiment, the present invention can be utilized in order to find and/or to locate providers and/or payers of, and for, respectively, various healthcare treatments, healthcare services and/or healthcare goods or products and/or healthcare-related goods or products. Information regarding the various providers and/or payers, along with information regarding the services and/or goods or products they provide and/or pay for, respectively, is stored in the database **10**H.

FIG. **10** illustrates another preferred embodiment method of utilizing the present invention. In the embodiment of FIG. **9**, the present invention can be utilized by any patient, user, provider, payer, and/or intermediary, in order to locate a provider and/or a payer of healthcare and/or healthcare-related services, goods, or products. For example, assume that a patient has been recently diagnosed as needing an operation to repair his vision. The patient or his provider would need to find a doctor who specializes in performing the needed surgical procedure. The present invention can thereafter be utilized to locate a specialist for performing that function.

With reference to FIG. **10**, operation of the apparatus **100** commences at step **1000**. At step **1001**, the patient or provider accesses that central processing computer **10** and provides information regarding the service needed. At step **1002**, the central processing computer **10** will process the request and identify one or more specialists along with their backgrounds, insurance coverage accepted, fees, and/or any educational, professional experience and/or any other infor-

mation about the provider. At step **1003**, the central processing computer **10** can generate a provider report and transmit same to the patient or provider at step **1004**. Thereafter, operation of the apparatus ceases at step **1005**.

In a similar manner, the embodiment of FIG. **10** can be utilized to find a facility for receiving a certain and/or desired form of care and/or for obtaining a certain procedure. In this embodiment, the facility is defined to be the provider and the present invention can be utilized as described above.

In another similar manner, the embodiment of FIG. **10** can be utilized to find a payer or insurance company for providing desired coverage and/or for paying for certain treatments and/or procedures. In the case of locating payers, the method of FIG. **10** can be repeated for locating payers for certain healthcare services, goods or products. At step **1001**, the patient or provider accesses that central processing computer **10** and provides information regarding the coverage needed. At step **1002**, the central processing computer **10** will process the request and identify one or more payers along with information about the payer or payers. At step **1003**, the central processing computer **10** can generate a payer report and transmit same to the patient or provider at step **1004**. Thereafter, operation of the apparatus ceases at step **1005**.

In another similar manner, the embodiment of FIG. **10** can be utilized to find and/or locate supplies, body organs, blood, medications, and/or any other goods, products, and/or supplies, etc. In this embodiment, the identification, location, cost, etc., of any of the above goods, products, supplies, organs etc., can be stored in the database **10H**.

With reference to FIG. **10**, operation of the apparatus **100** commences at step **1000**. At step **1001**, the patient or provider accesses that central processing computer **10** and provides information regarding the supply, body organ, blood, medication, and/or any other good, product, or supply or supplies needed. At step **1002**, the central processing computer **10** will process the request and identify the existence and/or location of the respective supply, body organ, blood, medication, and/or any other good, product, or supply or supplies, along with its location, cost and any other pertinent information. At step **1003**, the central processing computer **10** can generate a report and transmit same to the patient or provider at step **1004**. Thereafter, operation of the apparatus ceases at step **1005**.

In another similar manner, the embodiment of FIG. **10** can be utilized to find a payer or insurance company for providing desired coverage and/or for paying for certain treatments and/or procedures. In the case of locating payers, the method of FIG. **10** can be repeated for locating payers for certain healthcare services, goods or products. At step **1001**, the patient or provider accesses that central processing computer **10** and provides information regarding the coverage needed. At step **1002**, the central processing computer **10** will process the request and identify one or more payers along with information about the payer or payers. At step **1003**, the central processing computer **10** can generate a payer report and transmit same to the patient or provider at step **1004**. Thereafter, operation of the apparatus ceases at step **1005**.

The embodiment of FIG. **10** can also be utilized by intermediaries, such as insurance brokers who need to find certain insurance companies and/or payers who meet the needs of certain patients and/or clients, and/or other individuals and/or third parties.

In another preferred embodiment of FIG. **10**, any patient, user, provider, payer, and/or intermediary can request to be notified of the availability of a provider, the emergence of a patient in need of a certain care, the availability of a payer or an insurance company to offer a policy or a certain policy, the availability of a healthcare facility to provide certain care, the availability of certain supplies, a body organ, a blood type, an expiration of an insurance policy (i.e. healthcare insurance, life insurance, disability insurance, etc.,) and/or the occurrence of any event which may be of interest to any of the patients, users, providers, payers, and/or intermediaries, described herein.

In this embodiment, the party requesting to be notified of the event or occurrence, whichever it may be, (hereinafter the "requesting party"), can access the central processing computer **10** via their respective communication device. Thereafter, the requesting party can enter his request, provide any conditions attached to the request, and provide contact information. The central processing computer **10** can process the information received from the requesting party and store all pertinent information in the database **10H**.

Thereafter, another party (hereinafter the "supplying party") contacts the central processing computer **10**, either to enter information about the occurrence of an event and/or the availability of a service, a good or products, and/or any other herein-described and/or envisioned occurrence and/or good, product and/or service availability, or to review requests which have been previously submitted, which the supplying party may be interested in responding to.

If the entry of the supplying party can satisfy a request of a requesting party, and/or if the supplying party desires to satisfy a request of a requesting party, the central processing computer **10** will generate and/or transmit an e-mail message, a beeper or pager message, and/or a telephone call, and/or other communication to the communication device of the requesting party. The communication or message can include information for bring the requesting party and the supplying party together to act towards effecting and/or consummating the transaction. Thereafter, upon notification to the central processing computer by either the requesting party and/or the supplying party, or both, the central processing computer **10** can remove the request from the database **10H**. In this manner, the central processing computer **10** and/or the apparatus **100** can be utilized as a clearinghouse for effecting transactions for any of the services, goods, products, and/or any other entities described herein.

In another preferred embodiment, the present invention can be utilized to schedule appointments with any of the patients, providers, payers, and/or intermediaries, described herein. In this manner, for example, can make an appointment with the provider over the communication network which services the present invention.

FIGS. **11**A and **11**B illustrate another preferred embodiment method of using the present invention, in flow diagram form. In the embodiment of FIGS. **11**A and **11**B, provider scheduling information can be stored in the database **10H**. Operation of the apparatus **100** commences at step **1100**. At step **1101**, the patient accesses the central processing computer **10** and requests the schedule or schedules of a provider or a number of providers. At step **1102**, the central processing computer **10** provides the schedule information to the patient. At step **1103**, the patient can select the appointment he or she wishes to make.

At step **1104**, the appointment information is transmitted to and received at the central processing computer **10**. At step **1105**, the central processing computer **10** will update the provider's schedule to reflect the new appointment. At

step 1106, the central processing computer 10 will transmit a signal, such as an e-mail and/or other transmission and/or communication to provider communication device 20 to notify the provider and to update the providers schedule on the provider computer. In the preferred embodiment, the scheduling files stored on the database 10H of the central processing computer 10 and the database 20H on the provider communication device 20, and/or any portions and/or fields, or records, of same, can be dynamically linked to one another so that changes made to the schedule or schedules by either the central processing computer and/or on the provider communication device will be reflected in real-time so as to ensure that the most up-to-date schedules are available at all times.

Operation of the apparatus 100 will thereafter cease at step 1107. In another preferred embodiment, the central processing computer and/or the provider communication device can generate and/or transmit an e-mail to the patient communication device 40 in order to confirm the appointment and/or to serve as a reminder to the patient.

In the same manner, any patient, user, provider, payer, and/or intermediary can utilize the preferred embodiment of FIGS. 11A and 11B in order to schedule an appointment with any other patient, user, provider, payer, and/or intermediary, described herein.

In another preferred embodiment, the present invention can be utilized by intermediaries, such as, but not limited to brokers, insurance brokers, agents, and others, in order to service their respective clients. For example, the database 10H can contain insurance policy information, conditions, premiums, insurers providing same, as well as any other useful information in servicing insured's needs. The database 10H can also contain client information, policy requirements for any of the health insurance, life insurance, and/or disability insurance, policies in force for the insured along with premiums paid and/or expiration dates.

In another preferred embodiment, a broker, for example can prepare policy quotes, compare available policies, generate policies, and service policy claims via the information provided by the central processing computer 10 and/or the apparatus 100 of the present invention. The broker may also request to be notified, electronically and/or otherwise via a message generated and/or transmitted via the central processing computer 10, of times and/or instances when an insured's policy is up for renewal. The broker may then utilize any of the information provided by, and/or contained in, the database 10H of the present invention in order to respond to an insured client's needs and/or requests, such as, but not limited to preparing policy quotes for comparison, finding a policy and/or policies for addressing the insured's particular needs, assisting in resolving claims issues and/or claims processing issues, and/or assisting and/or providing any other information which could allow the broker or other intermediary to provide assistance to, and/or to provide added value to its client or clients.

In this, manner, the present invention can provide a platform for allowing a broker to provide improved services to his or her insured while also providing for a more paperless working relationship.

In another preferred embodiment of the present invention, the present invention can be utilized in order to provide notification to any of the patients, providers, payers, users, and/or intermediaries. For example, a medical specialist can be electronically arid/or otherwise notified if a patient is diagnosed with an illness and/or a condition which he or she specializes in treating. As another example, a payer can be electronically and/or otherwise notified when a patient may be admitted to a hospital and/or other facility for care. The present invention can also be utilized to electronically and/or otherwise notify a provider when his or her patient has been diagnosed with an illness even when the patient may not be under the provider's care, and/or to notify a patient if a provider has become available to perform a treatment and/or a procedure on, and/or for, the patient.

The present invention can also be utilized in order to provide notification, electronically and/or otherwise, to any respective party, regarding any event, happening, and/or occurrence, which is described herein and/or which may be reasonably foreseen from the comprehensive nature of the present invention in providing comprehensive healthcare processing.

FIGS. 12A and 12B illustrate another preferred embodiment method of utilizing the present invention, in flow diagram form. In the preferred embodiment of FIGS. 12A and 12B, the present invention can provide notification to any respective party, electronically and/or otherwise, in response to the occurrence of an event, happening, and/or occurrence. While the description of the embodiment of FIGS. 12A and 12B will be directed to notifying a doctor or other healthcare provider when a patient requires the provider's treatment and/or care, it is important to note that the embodiment of the FIGS. 12A and 12B can be utilized so as to provide notification services and/or functionality for any defined event, happening, and/or occurrence, and to any of the respective patients, users, providers, payers, and/or intermediaries, described herein.

The operation of the apparatus 100 commences at step 1200. At step 1201, the provider can access the central processing computer 10. At step 1202, the provider can select and/or enter the information concerning the notifying event, happening, and/or occurrence, and/or the conditions for notifying the provider. For example, an obstetrician can request to be notified when a pregnant patient enters a hospital in labor. At step 1203, the central processing computer 10 processes the above information. At step 1204, the central processing computer 10, upon receiving information concerning the pregnant patient's admission to the hospital, will process the pregnant patient's information.

At step 1205, the central processing computer 10 will identify and/or ascertain that the provider's condition for notification has been met or has been triggered. Thereafter, at step 1206, the central processing computer will generate an appropriate message to notify the provider. At step 1207, the central processing computer 10 can transmit the notification message to the provider's communication device as any one or more of an e-mail, a beeper or pager message, a telephone call, and/or in any other manner. The central processing computer 10 can also transmit multiple notification messages to multiple communication devices such as a computer, a personal digital assistant, a beeper or pager and/or a telephone. Thereafter, operation of the apparatus will cease at step 1208.

In a similar manner, a payer may also request to be notified upon the admission of a patient to a hospital and/or other care facility. A patient may also request that certain providers and/or payers be notified by the present invention of an event, happening, and/or occurrence involving the patient. There is no limit to the scenarios and/or alternate embodiments in which the present invention can be utilized in order to provide notification to any of the patients, users, providers, payers, and/or intermediaries, described herein.

In still another preferred embodiment, the present invention can be utilized to facilitate healthcare claims processing.

Any of the patients, providers, payers, users, and/or intermediaries, can file claims with the respective party electronically via the present invention. The claim forms for each payer and/or other party can be accessed from the respective party's communication device, filled out and submitted electronically by the claiming party or claimant. Any and/or all submissions can be electronically dated and/or otherwise marked, the status of the claim can be provided to the claimant at any time and any interested third parties may be notified of any action taken on a claim.

FIGS. 13A, 13B and 13C illustrate a method of utilizing the present invention to perform claims processing services. While it is understood that any appropriate party can file claims with any party described herein, for simplicity, a preferred embodiment where providers and/or patients file claims is described herein. The method, however, can be adapted for use by any party described herein.

With reference to FIGS. 13A, 13B and 13C, operation of the apparatus **100** commences at step **1300**. At step **1301**, the provider or patient, whichever the case may be, accesses the central processing computer **10** via the respective communication device **20** or **40**. At step **1302**, the provider or patient enters a request to make a claim. At step **1303**, the central processing computer **10** will record any information regarding the claim request and, thereafter, at step **1304**, link the provider or patient directly to the respective payer communication device **30**. At step **1305**, the provider or patient can request a claim form. At **1306**, the claim form will be transmitted from the payer communication device **30**, via the central processing computer **10**, which will record the occurrence of same, to the communication device **20** or **40** of the respective provider or patient. The provider or patient can fill out the form on the respective communication device **20** or **40** at step **1307**.

At step **1308**, the provider or patient transmits the completed form to the payer communication device **30** via the central processing computer **10** which will record the occurrence of same. At step **1309**, the payer will process the claim and, at step **1310**, generate a claim report or statement. At step **1311**, the claim report or statement is transmitted to the central processing computer **10**, which can record the occurrence as well as the action taken by the payer (i.e. claim approved or denied).

Thereafter, the central processing computer **10** will, at step **1312**, transmit the claim report or statement to the communication device **20** or **40**, respectively, of the provider or patient. Thereafter, at step **1313**, the provider or patient can provide the additional information and/or re-submit the claim form to the central processing computer. At step **1314**, the central processing computer **10** will determine if the provider or patient has provided additional information and/or has decided to resubmit the claim.

If, at step **1314**, it is determined that additional information has been provided and/or that the claim is to be re-submitted, the processing will proceed to step **1308** and the processing of steps **1308** through **1314** will be repeated until a resolution is reached between the parties involved. Thereafter, the operation of the apparatus **100** will cease at step **1315**. If at step **1314**, it is determined that no new additional information has been submitted and/or that the claim is not to be re-submitted then the operation of the apparatus **100** will cease at step **1315**.

In this manner, the present invention can facilitate an expedited and/or a paperless claim process. Further, records of the transactions, such as, but not limited to claim request, claim form request and/or delivery, claim submission, claim processing, claim report or statement, claim re-submission, provision of additional information, and/or any and/or all other transactions, which occur during the claim processing procedure or process, can be recorded and maintained at the central processing computer **10** so as to provide for a third party record and/or monitoring of same.

The central processing computer **10**, can notify any party described herein, as well as any third parties, regarding any event, happening, occurrence, and/or any aspect of any claim submission and/or processing activities. For example, a provider can be notified at regular interval on a payer's or payers decisions to pay for certain treatments and/or procedures. Similarly, a patient's employer can be notified regarding claim payments made by its group health insurer so as to ensure that its employees are being properly serviced and/or provided for. Other information may similarly be provided to any appropriate requesting party described herein and/or any qualified and/or appropriate third party. Notification can be provided to any appropriate party, via any of the communication methods and/or techniques described herein, and can be for, and/or include, any pertinent information.

In another preferred embodiment, the present invention can provide for automatic claim submission via the central processing computer **10** once a final diagnosis and treatment has been prescribed by a provider and/or upon the occurrence of an examination and/or the administration of a treatment. FIGS. **14**A and **14**B illustrate another preferred embodiment method of utilizing the present invention.

With reference to FIGS. **14**A and **14**B, operation of the apparatus **100** commences at step **1400**. At step **1401**, the patient's symptoms, if any, and/or examination findings are obtained from the patient and transmitted from the provider communication device **20** to the central processing computer **10**. The central processing computer **10** will, at step **1402** receive and process the patient symptoms, if any, and/or the examination findings, in conjunction with the patient's medical history and/or other information, medical theories, principles, criteria and/or other medical information needed to make a diagnosis. At step **1403**, the central processing computer **10** will perform a comprehensive diagnostic evaluation of the patient's symptoms, if any, and/or the examination findings.

At step **1404**, the central processing computer **10** will generate a diagnostic report which can include a diagnosis of the patient's condition. The diagnostic report which is generated at step **1404** can, if needed, include a single diagnosis and/or a list of possible diagnoses along with their respective probabilities, which may pertain to the patient's condition. At step **1405**, the central processing computer **10** can then generate, if needed, a treatment report which will outline and/or prescribe treatment for the single diagnosis and/or for the list of possible diagnoses. The central processing computer **10**, when generating the treatment report, can, if needed, process same in conjunction with, and consider, possible drug interactions and/or treatment interactions.

At step **1406**, the central processing computer **10** will transmit the diagnostic report and/or treatment report to the provider's communication device **20** at which point the medical doctor can obtain the diagnosis or possible diagnoses and corresponding treatment plans, if any. The medical doctor can then review the diagnostic report and/or treatment report and choose a final diagnosis and/or treatment plan to administer to the patient. At step **1407**, the medical doctor will transmit the final diagnosis and treat-

ment plan, including the prescribed treatment and/or treatment plan, to the central processing computer **10**. At step **1408**, the central processing computer will then update the patient's records in the database **10**H so as to include all of the data and information described as being processed and/or generated by the central processing computer **10**, including, but not limited to the patient's symptoms, the information contained in the diagnostic report and the treatment report, the final diagnosis and the prescribed treatment.

Thereafter, at step **1409**, the central processing computer **10** will generate a claim form which can meet the formal claim submission requirements of the patient's payer or insurance company. At step **1410**, the claim form will be submitted by the central processing computer **10** to the respective payer computer **30**. At step **1411**, any and/or all pertinent information regarding the claim submission, the patient, the provider visit, and/or any diagnoses and/or treatments considered, the final diagnosis and/or the prescribed treatment, can be stored and the patient's records will then be updated and be available for the patient's next treatment and/or diagnosis.

The operation of the apparatus **100** will then cease at step **1412**. In this manner, the present invention can provide for the automatic and/or for the programmed submission of healthcare claims, claim forms, claim requests, benefit requests, etc., upon the conclusion of a provider's service, consultation, treatment, procedure, and/or any other event which triggers coverage under a healthcare insurance policy and/or a payer's liability to pay for services and/or treatments.

The present invention can also be utilized, in the manner described above in connection with claiming healthcare insurance benefits, to claim disability insurance benefits and/or life insurance benefits.

In another preferred embodiment, the apparatus **100** can administer and/or maintain financial accounts for, and/or on behalf of, any of the patients, users, providers, payers, and/or intermediaries, described herein. In this manner, any of the parties described herein as utilizing the services of the apparatus **100**, and/or the central processing computer **10**, can have all financial transaction managed and/or monitored by the central processing computer **10**. In the preferred embodiment, the financial accounts can be conventional savings accounts, checking account, credit accounts, debit accounts, electronic money accounts, digital money accounts, etc., and/or any other appropriate account(s).

In the preferred embodiment, any of the respective parties may select to have the central processing computer **10** administer any financial transactions on their behalf. For example, a payer may deposit a sum of money which can be ear-marked for payment of healthcare provider services. A provider may open an account and deposit a sum of money to pay any vendor bills. The provider may also open an account to receive payment from payers and/or patients for services rendered. Each time a financial transaction is to occur, such as, for example, the payment from a payer to a provider resulting from a patient's claim, the central processing computer **10** will transfer funds (and/or deduct funds) from the payer's account and deposit the funds (and/or add the funds) to the providers account. Notwithstanding the examples provided above, the central processing computer **10** can effect any type of financial transaction (s) for, between, and/or on behalf of, any of the parties described herein.

The central processing computer **10**, in the preferred embodiment, can maintain detailed records of any and/or all of such transfer and/or transactions and provide periodic account statements to the respective parties maintaining accounts with the central processing computer **10**. In this manner, the present invention can provide an apparatus and a method for maintaining financial accounts, effecting financial transactions, and providing accounting and/or other notification services, for, and/or on behalf, any of the parties described herein.

In another preferred embodiment, the apparatus and method of the present can be utilized as healthcare training simulator for any of the providers, healthcare providers, healthcare professionals, and/or other providers described herein. The present invention can also be utilized by any user and/or individual wishing to learn about a certain healthcare field or topic. The present invention can be utilized to provide formal training, supplemental training, informal training, continuing education training, and/or any other training.

FIGS. **15**A and **15**B illustrates another preferred embodiment method for utilizing the present invention, in flow diagram form. The operation of the apparatus commences at step **1500**. At step **1501**, the individual utilizing the training simulator (referred to hereinafter as "the user") who could be any provider, student provider, and/or any other individual and/or party described herein, can access the central processing computer **10** via an appropriate computer or communication device. At step **1502**, the user can select the training program which he or she wishes to train from. At step **1503**, the central processing computer **10** will transmit the training scenario and/or information, including the symptoms and/or conditions of a hypothetical patient. The training scenario can include any one or more of: text information, a video tapped file or video clip, audio information, and/or any other multimedia information.

At step **1504**, the user can enter his or her diagnosis and prescribed treatment and/or treatments for the presented scenario and transmit same to the central processing computer **10**. At step **1505**, the user's diagnosis and prescribed treatment can be applied to the scenario. At step **1506**, the central processing computer **10** will compare the diagnosis against any diagnosis or diagnoses which are known to be correct and/or against any scientific and/or statistical norms. At step **1506**, the central processing computer **10** will apply the prescribed treatment or treatments to the hypothetical patient and compute a revised set of symptoms and/or conditions which can result from the applied treatment and/or treatments. Once again, statistical information can be utilized to arrive at a realistic response to the treatment and/or treatments. The user's diagnosis and prescribed treatment, as well as information regarding the correctness and/or viability of same can be recorded by the central processing computer **10** at step **1506**.

At step **1507**, the central processing computer **10** will transmit a response to the user's diagnosis and prescribed treatment. The response can include the patient's response to the prescribed treatment, and/or an evaluation of the diagnosis and prescribed treatment or treatments. The response can also include training materials, which can include any one or more of text information, video information, and/or audio information. At step **1508**, the user can review the material and/or information contained in the response and can decide whether he or she wishes to continue the training simulation. At step **1509**, the user will transmit a response to the central processing computer **10** which contains an instruction to either continue the simulation, in which case the user's response will also include a revised diagnosis and prescribed treatment or treatments, or to terminate the training simulation.

At step **1510**, the central processing computer **10** will receive and process the user's response provided at step **1509**. At step **1511**, the central processing computer **10** will determine whether the user desires to continue the simulation or whether the user desires to terminate the simulation. If, at step **1511**, it is determined that the user desires to continue the training simulation, the operation of the central processing computer **10** returns to step **1505** and the above-described process will be repeated from step **1505**. If, however, it is determined that the user desires to terminate the training simulation the operation of the apparatus **100** will cease at step **1512**. User responses, including diagnostic and treatment decisions, and/or performance, can be recorded and/or can be stored and, thereafter the information can be utilized to evaluate the user and/or for comparing the user's progress and/or improvements, as well as aptitude and skills, in the pertinent field of training, and/or the information can be utilized for any other useful purpose.

In this manner the apparatus and method of the present invention can be utilized to provide an interactive healthcare training simulator which can be utilized for training in any and/or all of the fields of medicine, surgery, psychiatry, psychology, psychotherapy, dentistry, oral surgery, nutrition, health and fitness, and/or in any other healthcare and/or healthcare -related field.

Data and/or information collected and/or stored by the apparatus **100**, which relates to symptoms and/or conditions, as well as responses to treatments, can be utilized in order to present realistic and confidential training scenarios. In this manner, the present invention can be utilized to compile a vast amount of information relating to the various fields of healthcare. The information can then be utilized to provide realistic training for providers and/or student providers. In this manner, the present invention can utilize information obtained from other preferred embodiments in order to provide simulated training scenarios.

In any and/or all of the embodiments described herein, any patient, provider, payer, user, and/or intermediary can access any one or more of the central processing computer (s) **10**, the providers communication devices **(20)**, the payer communication devices **30**, the patient communication devices **40**, and/or the intermediate communication devices **50**, via any one or more of the said computers and/or communication devices **10**, **20**, **30**, **40**, and/or **50**, as well as via any computer and/or communication device. In this manner, any of the herein-described parties can access the present invention from any computer and/or communication device. Public kiosks with links to any of the computers and/or communication devices **10**, **20**, **30**, **40**, and/or **50**, can also be utilized to access and utilize the present invention and/or any of the computers and/or communication devices described herein.

In any and/or all of the embodiments described herein, access to any and/or all of the data, information, records files, etc., which is stored in any of the databases **10H**, **20H**, **30H**, **40H**, and/or **50H**, can be restricted to preserve the security and confidentiality of same. Any of the patients, users, providers, payers, and/or intermediaries, can be provided with identification and/or other cards with any and/or all pertinent data regarding the respective individual and/or party provided on the card.

The identification card, in the preferred embodiment can contain a magnetic strip for storing any and/or all pertinent information, a "smart card" for storing information, and/or a bar code or bard codes for storing identification information as well as any other information described herein as being pertinent to the respective patient, user, provider, payer, and/or intermediary.

Each of the central processing computer(s) **10**, the providers communication devices **20**, the payer communication devices **30**, the patient communication devices **40**, and/or the intermediate communication devices **50**, as well as any other computer and/or communication device, can include suitable devices for reading, scanning, and/or obtaining information which may be stored on the identification card. In this manner, access to the present invention, and the respective use thereof, can be facilitated by the above-described identification card(s).

In another preferred embodiment, as well as in any of the embodiments described herein, intelligent agents, software agents, mobile agents, and/or related technologies, can be utilized in conjunction with the present invention. The respective intelligent agent(s), software agent(s), mobile agent(s), (hereinafter referred to collectively as "intelligent agent" or "intelligent agents") can be programmed and/or designed to act on behalf of the respective patients, users, providers, payers, and/or intermediaries, so as to act on behalf of the respective party as well as to perform any of processing functions and/or other functions described herein.

The intelligent agent can act on behalf of the respective party in various related interactions and/or other activities which are described as being performed herein and/or which may be incidental and/or related thereto. Therefore, the present invention also provides an agent-based apparatus and method for providing healthcare information and/or healthcare-related information.

Applicant hereby incorporates by reference herein the subject matter of the *Agent Sourcebook, A Complete Guide to Desktop, Internet and Intranet Agents*, by Alper Caglayan and Colin Harrison, Wiley Computer Publishing, 1997. Applicant also incorporates by reference herein the subject matter of *Cool Intelligent Agents For The Net*, by Leslie L. Lesnick with Ralph E. Moore, IDG Books Worldwide, Inc. 1997.

The apparatus of the present invention, in any and/or all of the embodiments described herein, can also be programmed to be self-activating and/or activated automatically.

The apparatus of the present invention can also be programmed in order to automatically generate and/or transmit any of the e-mails, electronic message transmissions, electronic notification transmissions, and/or any of the communications, which are described herein, between any of the parties which utilize the present invention.

The present invention, in any and/or all of the herein-described embodiments, can utilize electronic commerce technologies and security methods, techniques and technologies, as described and as set forth in *Electronic Commerce Technical, Business, and Legal Issues*, Nabil R. Adam, et al. Prentice Hall, 1999 and *Web Security & Commerce*, Simson Garfinkel with Gene Spafford, O'Reilly 1997, the subject matter of which are hereby incorporated by reference herein.

The communications networks and/or systems on, or over, which the present invention may be utilized, can include any one or combination of telecommunication networks or systems, satellite communication networks or systems, radio communication networks or systems, digital communication networks or systems, digital satellite communication networks or systems, personal communications services networks or systems, cable television networks or

systems, broadband communication networks or systems, low earth orbiting satellite (LEOs) networks or systems, wireless communication networks or systems, wireless Internet networks or systems, wireless World Wide Web networks or systems, as well as in, or on any internets and/or intranets, the Internet, the World Wide Web, and any other suitable communication network or system.

The data and/or information, described as being stored in the database **10**H and/or in any of the other databases described herein, can be continuously updated so as to store the latest values for the data and/or information and can be stored and be made available for future processing routines.

Any and/or all of the data and/or information described herein, which is stored in the database **10**H, or in the collection of databases, can be linked via relational database techniques and/or via any appropriate database management techniques. The data and/or information, in the preferred embodiments, can be updated via inputs from any of the computers and/or communication devices **10**, **20**, **30**, **40**, and/or **50**, and/or external computers or communication devices, described herein, in real-time, and/or via dynamically linked database management techniques. The above-described updates can also be provided from other information sources via the communication network.

The data and/or information which is stored in the database **10**H and/or which may be otherwise utilized with, and/or in conjunction with, the apparatus and method of the present invention, can be linked via any suitable data linking techniques such as, for example, dynamically linked lists (DLLs), linked lists, and object links embedded (OLE's). Any suitable database management technique(s) may also be utilized in conjunction with the present invention.

The present invention provides an apparatus and a method for providing comprehensive information in the healthcare fields and/or healthcare-related fields. The present invention also provides valuable services to the various parties who seek, provide, pay for, administer, and/or monitor healthcare services, goods and/or products as well as healthcare-related services, goods, and/or products.

The present invention can provide comprehensive and accurate information to any of the parties described herein so as to facilitate an improved healthcare system which can provide up-to-date patient, provider, payer, and/or intermediary, information. The present invention, by facilitating the creation and maintenance of a comprehensive database of information, which can be accessed on a global basis, at any time of day or night, and from any location, can provide patients, providers, payers, and/or intermediaries, with information which can improve healthcare treatments, reduce the likelihood of errors in diagnoses and/or prescribed treatments, reduce healthcare costs, reduce the likelihood of incorrect and/or fraudulent care, and can provide for a healthcare system which is characterized by an improved quality of care and cost efficiency.

In addition to any and/or all of the preferred embodiments described herein, the present invention can also be utilized in other preferred embodiments so as to incorporate, so as to improve upon, and/or so as to utilize, various teachings of the prior art. In this regard, Applicant hereby incorporates by reference herein the subject matter of the following U.S. Patents: U.S. Pat. No. 5,988,851 which teaches a medical treatment and or diagnostic system; U.S. Pat. No. 5,974,124 which teaches a methods and system aiding medical diagnosis and treatment; U.S. Pat. No. 5,961,448 which teaches a virtual medical instrument for performing medical diagnostic testing on patients; U.S. Pat. No. 5,957,854 which teaches a wireless medical diagnosis and monitoring equipment; U.S. Pat. No. 5,954,641 which teaches a method, apparatus and operating system for managing the administration of medication and medical treatment regimens; U.S. Pat. No. 5,935,060 which teaches a computerized medical diagnostic and treatment advice system including list based processing; U.S. Pat. No. 5,910,107 which teaches a computerized medical diagnostic and treatment advice method; U.S. Pat. No. 5,899,857 which teaches a medical treatment method with scanner input; U.S. Pat. No. 5,895,354 which teaches an integrated medical diagnostic center; U.S. Pat. No. 5,878,746 which teaches a computerized medical diagnostic system; U.S. Pat. No. 5,876,351 which teaches a portable modular diagnostic medical device; U.S. Pat. No. 5,868,669 which teaches a computerized medical diagnostic and treatment advice system; U.S. Pat. No. 5,862,803 which teaches a wireless medical diagnosis and monitoring system; U.S. Pat. No. 5,839,438 which teaches a computer-based neural network system and method for medical diagnosis and interpretation; U.S. Pat. No. 5,807,256 which teaches a medical information processing system for supporting diagnosis; U.S. Pat. No. 5,807,246 which a display device in medical examination and treatment system; U.S. Pat. No. 5,801,755 which teaches an interactive communication system for medical treatment of remotely located patients; U.S. Pat. No. 5,797,901 which teaches an automatic activation system for a medical diagnostic monitoring and surgical apparatus and method therefore; U.S. Pat. No. 5,779,634 which teaches a medical information processing system for supporting diagnosis; U.S. Pat. No. 5,776,057 which teaches a virtual medical instrument for performing medical diagnostic testing on patients; U.S. Pat. No. 5,761,334 which teaches an apparatus for computer aided diagnosis of medical images having abnormal patterns; U.S. Pat. No. 5,724,968 which teaches a computerized medical diagnostic system including meta function; U.S. Pat. No. 5,666,953 which teaches a system and associated method for providing information for use in forming medical diagnosis; U.S. Pat. No. 5,660,176 which teaches a computerized medical diagnostic and treatment advice system; U.S. Pat. No. 5,594,638 which teaches a computerized medical diagnostic system including re-enter function and sensitivity factors; U.S. Pat. No. 5,583,758 which teaches a medical health care management system for managing medical treatments and comparing user-proposed and recommended resources required for treatment; U.S. Pat. No. 5,551,436 which teaches a medical diagnosis system; U.S. Pat. No. 5,544,651 which teaches a medical system and associated method for automatic treatment; U.S. Pat. No. 5,437,278 which teaches medical diagnosis system and method; U.S. Pat. No. 5,415,167 which teaches a medical system and associated method for automatic diagnosis and treatment; U.S. Pat. No. 5,360,005 which teaches a medical diagnosis device for sensing cardiac activity and blood flow; U.S. Pat. No. 5,331,550 which teaches an application of neural networks as an aid in medical diagnosis and general anomaly detection; U.S. Pat. No. 5,324,077 which teaches a medical data draft for tracking and evaluating medical treatment; U.S. Pat. No. 5,305,748 which teaches a medical diagnostic system and related method; U.S. Pat. No. 5,279,294 which teaches a medical diagnostic system; U.S. Pat. No. 5,255,187 which teaches a computer aided medical diagnostic method and apparatus; U.S. Pat. No. 5,235,510 which teaches a computer-aided diagnosis system for medical use; U.S. Pat. No. 5,090,417 which teaches a medical diagnostic apparatus; U.S. Pat. No. 4,733,354 which teaches a method and apparatus for automated medical diagnosis using decision tree analysis; U.S. Pat. No.

4,731,725 which teaches a data processing system which suggests a pattern of medical tests to reduce the number of tests necessary to confirm or deny a diagnosis; U.S. Pat. No. 4,674,512 which teaches a medical electrode for monitoring and diagnostic use; U.S. Pat. No. 4,674,108 which teaches a digital X-ray medical diagnostic apparatus; U.S. Pat. No. 4,641,659 which teaches a medical diagnostic microwave scanning apparatus; U.S. Pat. No. 4,290,114 which teaches a medical diagnostic computer; U.S. Pat. No. 4,251,850 which teaches a control desk for medical apparatus, in particular for an x-ray diagnostic apparatus; U.S. Pat. No. 4,242,911 which teaches an ultrasonic medical diagnostic apparatus and method; U.S. Pat. No. 4,235,454 which teaches a stabilization system for a medical diagnostic device; U.S. Pat. No. 4,209,022 which teaches an echography apparatus for medical diagnosis, using a multiple-element probe; U.S. Pat. No. 4,170,987 which teaches a medical diagnosis system and method with multispectral imaging; U.S. Pat. No. 4,110,723 which teaches an ultrasonic apparatus for medical diagnosis; and U.S. Pat. No. 3,978,850 which teaches medical diagnostic instruments.

While the present invention has been described and illustrated in various preferred and alternate embodiments, such descriptions are merely illustrative of the present invention and are not to be construed to be limitations thereof. In this regard, the present invention encompasses all modifications, variations and/or alternate embodiments, with the scope of the present invention being limited only by the claims which follow.

What is claimed is:

1. In an apparatus for providing healthcare information, said apparatus comprising a processor for processing at least one of symptom information and condition information corresponding to a patient, in conjunction with at least one of healthcare information, healthcare theories, healthcare principles, and healthcare research, wherein said processor generates a diagnostic report, and further wherein said diagnostic report contains information regarding at least one of a diagnosis and a possible diagnosis for the at least one of symptom information and condition information, the improvement comprising:

said processor generating a diagnostic report containing at least one of a diagnosis, a possible diagnosis, and a list of possible diagnoses, wherein said improved apparatus further coimprises:

a transmitter for transmitting said diagnostic report to at least one of a computer and a communication device associated with a healthcare provider; and

a receiver for receiving a final diagnosis from said at least one of a computer and a communication device associated with the healthcare provider, and further wherein said processor generates a claim form for submission to at least one of a healthcare payer and a healthcare insurer.

2. The apparatus of claim 1, wherein said diagnostic report contains at least one of probability information and. statistical information associated with the possible diagnoses.

3. The apparatus of claim 1, wherein said processor generates a treatment report, wherein said treatment report contains at least one of treatment information for the possible diagnoses, drug interaction information, and treatment interaction information.

4. The apparatus of claim 3, wherein said transmitter transmits said claim form to at least one of a computer and a communication device associated with the at least one of a healthcare payer and a healthcare insurer.

5. The apparatus of claim 1, wherein said processor updates a patient file to include information regarding the final diagnosis.

6. The apparatus of claim 3, wherein at least one of said diagnostic report and said treatment report contains at least one of healthcare information, medical information, textbook materials, reference materials, video information, audio information, a link to information, health information, wellness information, fitness information, treatment information, treatment warning information, misdiagnosis warning information, experimental treatment information, treatment success information, treatment failure information, treatment information, and treatment procedure information.

7. The apparatus of claim 1, wherein said receiver receives treatment information regarding a treatment to be administered to a patient, and further wherein said processor processes said treatment information in conjunction with at least one of said diagnostic report and said treatment report, and further wherein said processor generates a treatment response message, wherein said treatment response message contains information for at least one of verifying a treatment to be performed as being correct and providing information for correcting an incorrect treatment.

8. The apparatus of claim 1, further comprising:

an input device for inputting information regarding at least one of healthcare information, patient information, and a command, into said apparatus; and

at least one of a display device for displaying information at least one of processed by and provided by the apparatus and an output device for outputting information at least one of processed by and provided by the apparatus.

9. The apparatus of claim 1, wherein said healthcare information is at least one of medical information, surgical information, psychiatric information, psychological information, and dental information.

10. In an apparatus for providing healthcare information, said apparatus comprising a processor for processing at least one of symptom information and condition information corresponding to a patient, in conjunction with at least one of healthcare information, healthcare theories, healthcare principles, and healthcare research, wherein said processor generates at least one of a diagnostic report and a treatment report, wherein said diagnostic report contains information regarding at least one of a diagnosis and a possible diagnosis for the at least one of symptom information and condition information, and wherein said treatment report contains information regarding a treatment for the at least one of a diagnosis and a possible diagnosis, the improvement comprising:

a receiver for receiving treatment information regarding a treatment to be administered to a patient, wherein said treatment information is received from at least one of a computer and a communication device associated with a healthcare provider, wherein said processor processes said treatment information in conjunction with said at least one of a diagnostic report and a treatment report, and further wherein said processor generates a treatment response message, wherein said treatment response message contains information for at least one of verifying a treatment to be performed as being correct and providing information for correcting an incorrect treatment; and

a transmitter for transmitting said treatment response message to the at least one of a computer and communication device associated with the healthcare provider.

11. The apparatus of claim 10, wherein said treatment response message contains information regarding at least one of a treatment, a procedure, treatment instructions, procedure instructions, treatment steps, and procedure steps.

12. The apparatus of claim 10, wherein at least one of said diagnostic report, said treatment report, and said treatment response message, contains at least one of textbook materials, reference materials, video information, audio information, a link to information, treatment information, treatment warning information, experimental treatment information, treatment success information, and treatment failure information.

13. The apparatus of claim 10, wherein said healthcare information is at least one of medical information, surgical information, psychiatric information, psychological information, and dental information.

14. In a method for providing healthcare information, said method comprising processing at least one of symptom information and condition information corresponding to a patient, in conjunction with at least one of healthcare information, healthcare theories, healthcare principles, and healthcare research, and generating a diagnostic report, wherein said diagnostic report contains information regarding at least one of a diagnosis and a possible diagnosis for the at least one of symptom information and condition information, the improvement comprising:

generating a diagnostic report containing at least one of a diagnosis, a possible diagnosis, and a list of possible diagnoses;

transmitting said diagnostic report to at least one of a computer and a communication device associated with a healthcare provider;

receiving a final diagnosis from said at least one of a computer and a communication device associated with the healthcare provider; and

generating a claim form for submission to at least one of a healthcare payer and a healthcare insurer.

15. The method of claim 14, wherein said diagnostic report contains at least one of probability information and statistical information associated with the possible diagnoses.

16. The method of claim 14, further comprising:

generating a treatment report, wherein said treatment report contains treatment information for the possible diagnoses.

17. The method of claim 16, wherein said treatment report contains at least one of drug interaction information and treatment interaction information.

18. The method of claim 14, further comprising:

updating a patient file to include information regarding the final diagnosis.

19. The method of claim 14, further comprising;

receiving treatment information regarding a treatment to be administered to a patient;

processing said treatment information in conjunction with at least one of said diagnostic report and said treatment report; and

generating a treatment response message, wherein said treatment response message contains information for at least one of verifying a treatment to be performed as being correct and providing information for correcting an incorrect treatment.

20. The method of claim 14, wherein said healthcare information is at least one of medical information, surgical information, psychiatric information, psychological information, and dental information.

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(54) METHOD AND SYSTEM FOR MANAGING PATIENT MEDICAL RECORDS

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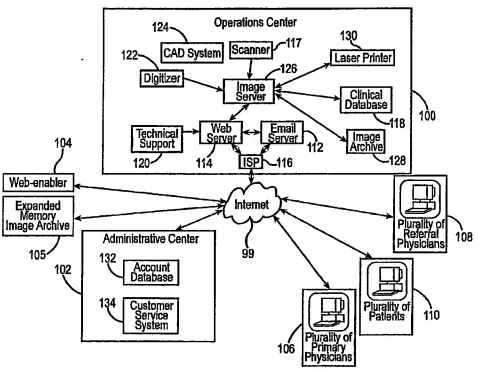
(52) U.S. Cl. 705/3

(57) ABSTRACT

A method and system for providing a medical record management service that supports the creating, storing, accessing, updating, and distributing of patient medical records, especially diagnostic-quality medical imaging, under the control of a patient and the coordinated care of the patient and her physician. According to a representative embodiment, the present invention includes a scanner, a clinical database, an account database, a digitizer, an e-mail server, an image server with an image archive, a web server, an Internet service provider, a web enabler, an expanded memory image archive, and a series of Internet-based software applications and graphical user interfaces that give the patients and physicians access to view and manipulate the information in the clinical database and image archives. The present invention can further include computer-aided detection and a printer capable of producing diagnostic-quality images.



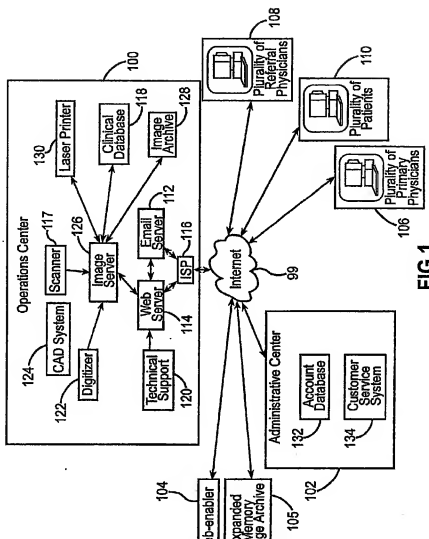

Operations Center
100
Laser Printer
130
Clinical Database
118
Image Archive
128
Scanner
117
126
Image Server
Email Server
112
CAD System
124
Digitizer
122
Web Server
114
LSP
116
Technical Support
120
Internet
99
Plurality of Referral Physicians
108
Plurality of Patients
110
Plurality of Primary Physicians
106
Administrative Center
Account Database
132
Customer Service System
134
102
Web-enabler
104
Expanded Memory Image Archive
105

FIG. 1

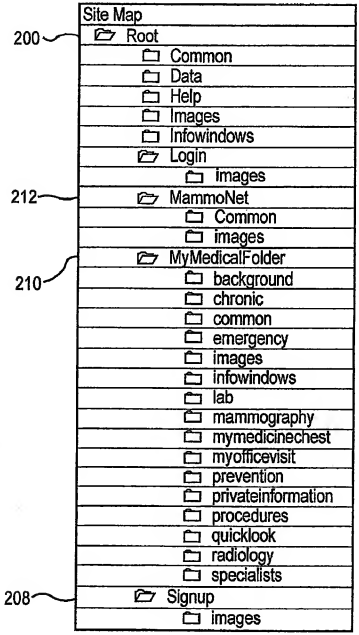

Site Map
200
Root
Common
Data
Help
Images
Infowindows
Login
images
212
MammoNet
Common
images
MyMedicalFolder
210
background
chronic
common
emergency
images
infowindows
lab
mammography
mymedicinechest
myofficevisit
prevention
privateinformation
procedures
quicklook
radiology
specialists
208
Signup
images

FIG.2a

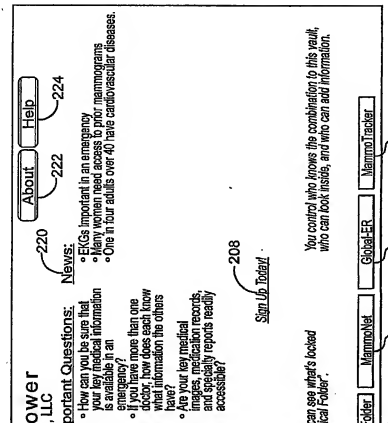

Patient Power
Global TeleImaging, LLC
About
Help
224
222
220
News:
• ECGs important in an emergency
• Many women need access to prior mammograms
• One in four adults over 40 have cardiovascular diseases.
Important Questions:
• How can you be sure that your key medical information is available in an emergency?
• If you have more than one doctor, how does each know what information the others have?
• Are your key medical images, medication records, and specialty reports readily accessible?
208
Sign Up Today!
Without authorization, no one can see what's locked up inside your personal "Medical Folder".
You control who knows the combination to this vault, who can look inside, and who can add information.
My Medical Folder
MammoNet
Global-ER
MammoTracker
210
212
214
216

FIG.2b

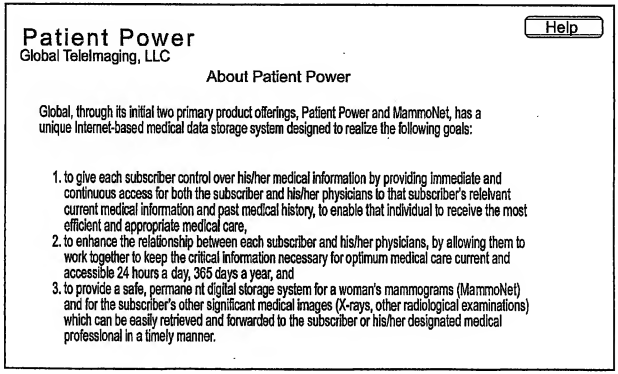

Help
Patient Power
Global TeleImaging, LLC
About Patient Power
Global, through its initial two primary product offerings, Patient Power and MammoNet, has a unique Internet-based medical data storage system designed to realize the following goals:
1. to give each subscriber control over his/her medical information by providing immediate and continuous access for both the subscriber and his/her physicians to that subscriber's relelvant current medical information and past medical history, to enable that individual to receive the most efficient and appropriate medical care,
2. to enhance the relationship between each subscriber and his/her physicians, by allowing them to work together to keep the critical information necessary for optimum medical care current and accessible 24 hours a day, 365 days a year, and
3. to provide a safe, permane nt digital storage system for a woman's mammograms (MammoNet) and for the subscriber's other significant medical images (X-rays, other radiological examinations) which can be easily retrieved and forwarded to the subscriber or his/her designated medical professional in a timely manner.

FIG.2c

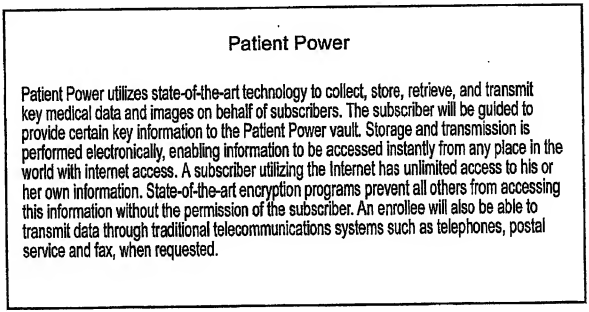

Patient Power
Patient Power utilizes state-of-the-art technology to collect, store, retrieve, and transmit key medical data and images on behalf of subscribers. The subscriber will be guided to provide certain key information to the Patient Power vault. Storage and transmission is performed electronically, enabling information to be accessed instantly from any place in the world with internet access. A subscriber utilizing the Internet has unlimited access to his or her own information. State-of-the-art encryption programs prevent all others from accessing this information without the permission of the subscriber. An enrollee will also be able to transmit data through traditional telecommunications systems such as telephones, postal service and fax, when requested.

FIG.2d

Patient Power is designed with the physician in mind and sees the physician as a crucial partner for success. Consistent with that approach, Patient Power has designed multiple ways in which physicians can choose to participate in the program.

Under one scenario, a physician or medical practice utilizes the Patient Power My Office Visit form in its own medical records and supplies copies to the patient and vice versa. In adopting this approach, practitioners agree that the overall result is better patient compliance, more efficient, faster visits, increased patient satisfaction, and improved patient follow-up.

FIG.2e

My Medical Folder is structured to include radiology (X-ray) reports and significant medical images stored within the patient's vault. To the degree that certain studies such as CT and MRI scans are digital and can be viewd on PC monitors for diagnostic purposes, these images will actually be digitally available in a patient's vault and available for transmission to any practitioner needing to view the images. Patient Power differs dramatically in this regard from other digital image storage systems (PACS). Those systems are proprietary and their contents are owned by the provider producing those images, such as a hospital, clinic, HMO, or practitioner's office. With Patient Power, the subscriber controls these images, and therefore has continuous access to them for review by any healthcare provider or other individual or institution designated by that subscriber.

Return

FIG.2f

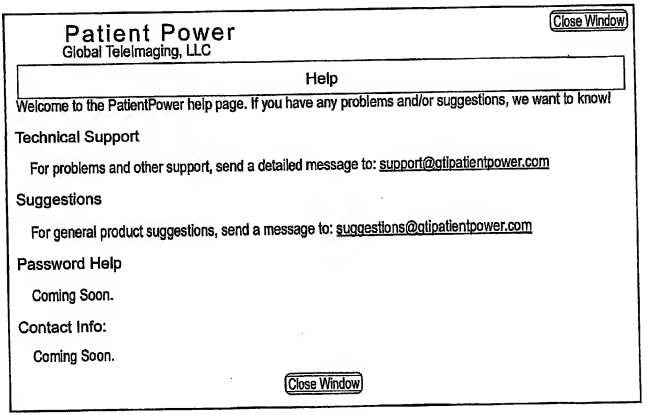

Patient Power
Global Telelmaging, LLC
Close Window
Help
Welcome to the PatientPower help page. If you have any problems and/or suggestions, we want to know!
Technical Support
For problems and other support, send a detailed message to: support@gtipatientpower.com
Suggestions
For general product suggestions, send a message to: suggestions@gtipatientpower.com
Password Help
Coming Soon.
Contact Info:
Coming Soon.
Close Window

FIG.2g

Tab	Product			
	My Medical Folder	Global-ER**	MammoTracker	MammoNet
Background	✓	✓	✓	✓
Chronic	✓	✓		
Emergency	✓	✓		
Lab	✓			
Mammography	✓		✓	✓
MammoTracker	✓	✓	✓	
Mammography Images				✓
Miriuma				✓
Mymedicine Chest	✓	✓		
My Office Visit	✓			
Prevention	✓			
Private Information Including Flex Spending Tracker, Copayment Tracker, etc.	✓			
Procedures	✓			
Quicklook	✓	✓		
Radiology	✓			
Specialists	✓			
Ultrasound				✓

**Note: Global-ER includes the ability to include an EKG and two additional key reports.

FIG.2h

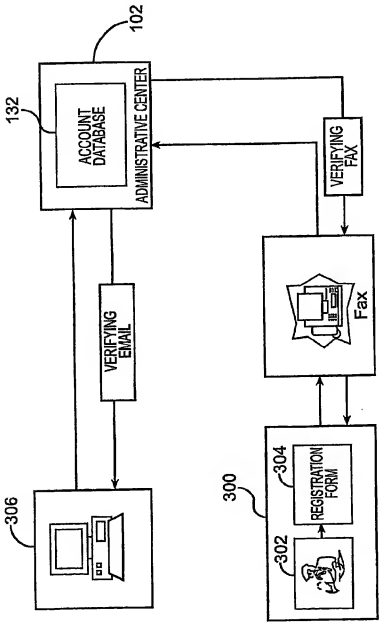

102
132
ACCOUNT DATABASE
ADMINISTRATIVE CENTER
VERIFYING FAX
VERIFYING EMAIL
Fax
306
300
304
REGISTRATION FORM
302

FIG.3a

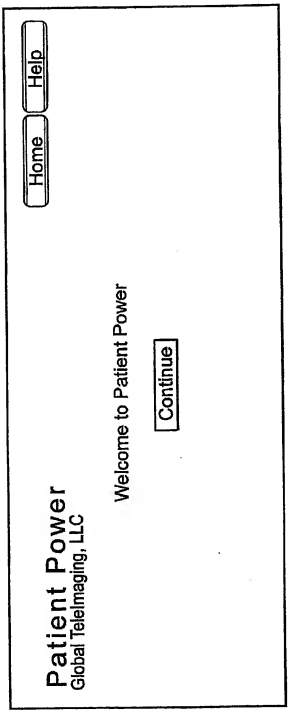

Home
Help
Patient Power
Global Telelmaging, LLC
Welcome to Patient Power
Continue

FIG.3b

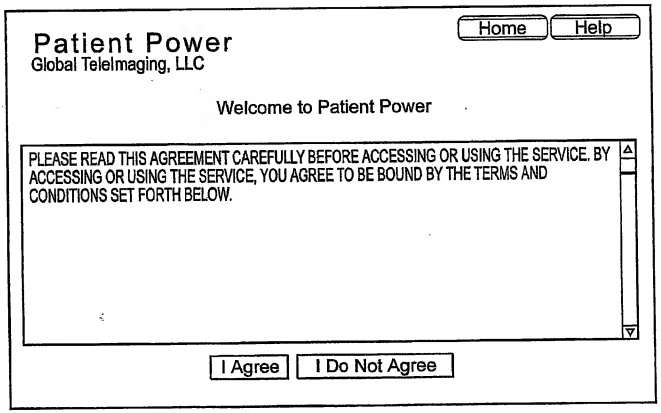

Patient Power
Global TeleImaging, LLC
Home
Help
Welcome to Patient Power
PLEASE READ THIS AGREEMENT CAREFULLY BEFORE ACCESSING OR USING THE SERVICE. BY ACCESSING OR USING THE SERVICE, YOU AGREE TO BE BOUND BY THE TERMS AND CONDITIONS SET FORTH BELOW.
I Agree
I Do Not Agree

FIG.3c

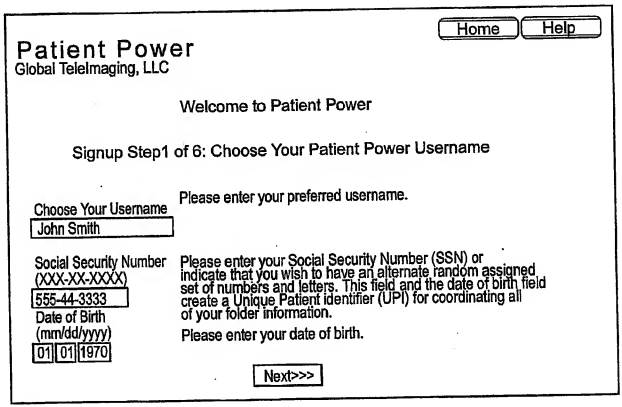

Home
Help
Patient Power
Global TeleImaging, LLC
Welcome to Patient Power
Signup Step1 of 6: Choose Your Patient Power Username
Choose Your Username
John Smith
Please enter your preferred username.
Social Security Number
(XXX-XX-XXXX)
555-44-3333
Please enter your Social Security Number (SSN) or indicate that you wish to have an alternate random assigned set of numbers and letters. This field and the date of birth field create a Unique Patient identifier (UPI) for coordinating all of your folder information.
Date of Birth
(mm/dd/yyyy)
01 01 1970
Please enter your date of birth.
Next>>>

FIG.3d

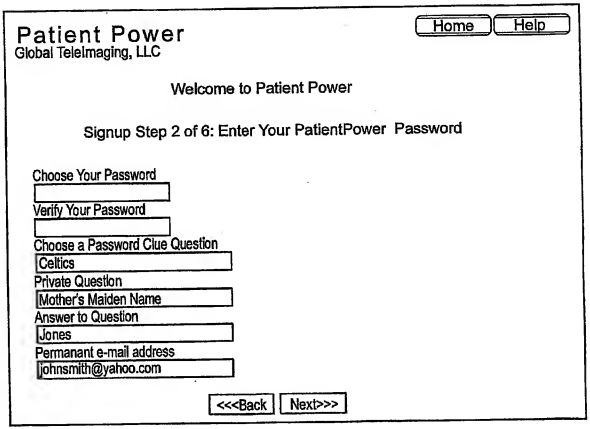

Patent Power
Global TeleImaging, LLC
Home
Help
Welcome to Patient Power
Signup Step 2 of 6: Enter Your PatientPower Password
Choose Your Password
Verify Your Password
Choose a Password Clue Question
Celtics
Private Question
Mother's Maiden Name
Answer to Question
Jones
Permanant e-mail address
johnsmith@yahoo.com
<<<Back
Next>>>

FIG.3e

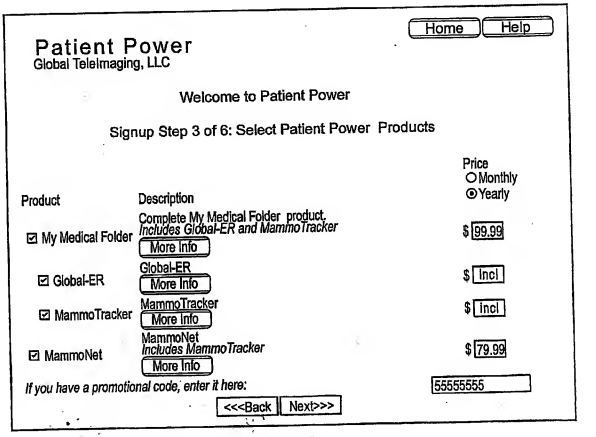

Home
Help
Patient Power
Global TeleImaging, LLC
Welcome to Patient Power
Signup Step 3 of 6: Select Patient Power Products
Price
Monthly
Yearly
Product
Description
My Medical Folder
Complete My Medical Folder product.
Includes Global-ER and MammoTracker
More Info
$ 99.99
Global-ER
Global-ER
More Info
$ Incl
MammoTracker
MammoTracker
More Info
$ Incl
MammoNet
MammoNet
Includes MammoTracker
More Info
$ 79.99
If you have a promotional code, enter it here:
55555555
<<<Back
Next>>>

FIG.3f

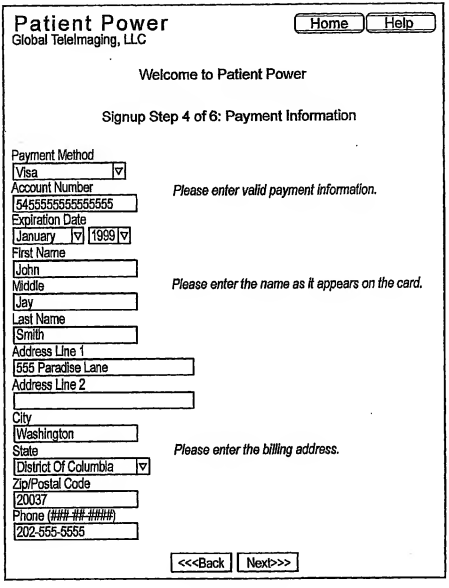

Patient Power
Global Telelmaging, LLC
Home
Help
Welcome to Patient Power
Signup Step 4 of 6: Payment Information
Payment Method
Visa
Account Number
5455555555555555
Please enter valid payment information.
Expiration Date
January
1999
First Name
John
Middle
Jay
Please enter the name as it appears on the card.
Last Name
Smith
Address Line 1
555 Paradise Lane
Address Line 2
City
Washington
State
District Of Columbia
Please enter the billing address.
Zip/Postal Code
20037
Phone (### ## ####)
202-555-5555
<<<Back
Next>>>

FIG.3g

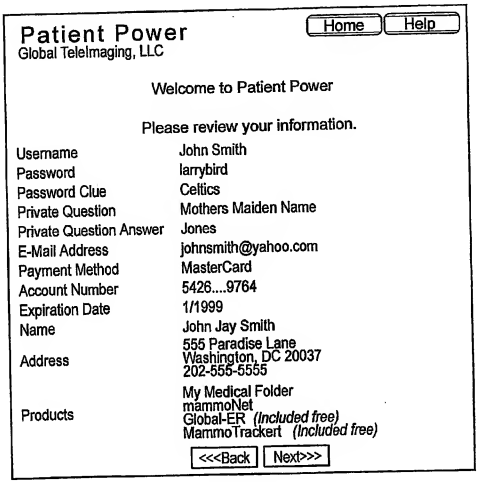

Patient Power
Global Telelmaging, LLC
Home
Help
Welcome to Patient Power
Please review your information.
Username
John Smith
Password
larrybird
Password Clue
Celtics
Private Question
Mothers Maiden Name
Private Question Answer
Jones
E-Mail Address
johnsmith@yahoo.com
Payment Method
MasterCard
Account Number
5426....9764
Expiration Date
1/1999
Name
John Jay Smith
Address
555 Paradise Lane
Washington, DC 20037
202-555-5555
Products
My Medical Folder
mammoNet
Global-ER (Included free)
MammoTrackert (Included free)
<<<Back
Next>>>

FIG.3h

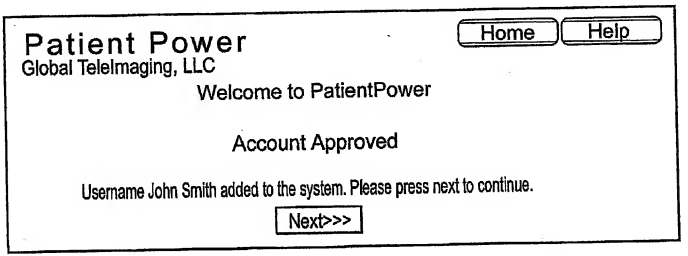

Patient Power
Global TeleImaging, LLC
Home
Help
Welcome to PatientPower
Account Approved
Username John Smith added to the system. Please press next to continue.
Next>>>

FIG.3i

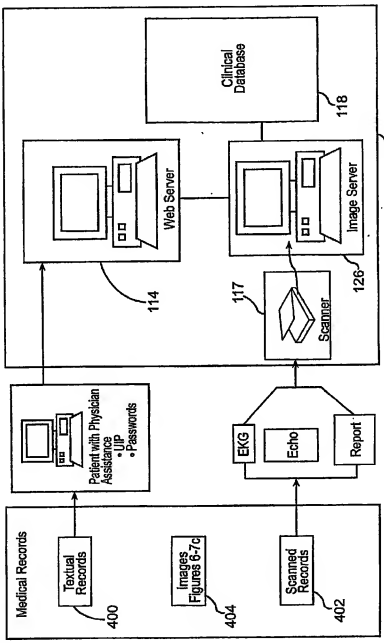

Medical Records
Textual Records
400
Images Figures 6-7c
404
Scanned Records
402
Patient with Physician Assistance
•UIP
•Passwords
EKG
Echo
Report
Scanner
117
Web Server
114
Image Server
126
Clinical Database
118
100

FIG.4

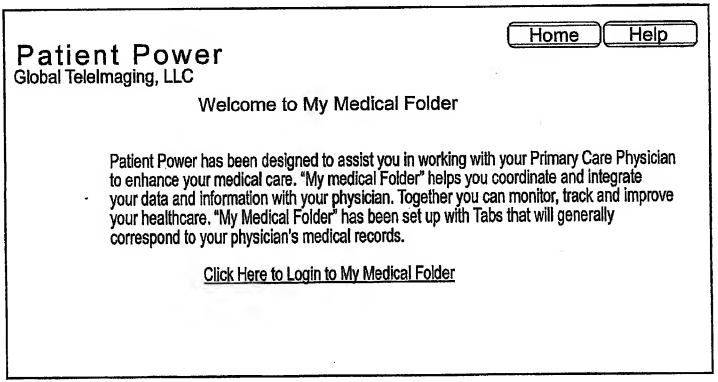

Home
Help
Patient Power
Global TeleImaging, LLC
Welcome to My Medical Folder
Patient Power has been designed to assist you in working with your Primary Care Physician to enhance your medical care. "My medical Folder" helps you coordinate and integrate your data and information with your physician. Together you can monitor, track and improve your healthcare. "My Medical Folder" has been set up with Tabs that will generally correspond to your physician's medical records.
Click Here to Login to My Medical Folder

FIG.5a

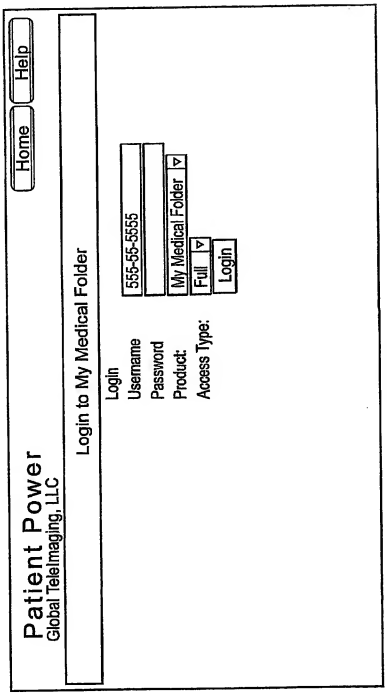

Patent Power
Global TeleImaging, LLC
Home
Help
Login to My Medical Folder
Login
Username
555-55-5555
Password
Product:
My Medical Folder
Access Type:
Full
Login

FIG.5b

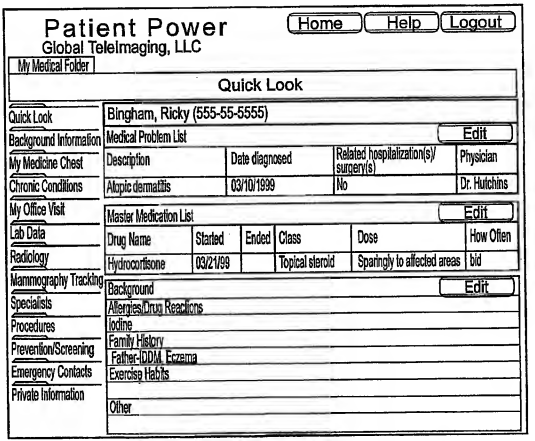

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Quick Look
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Medical Problem List
Edit
Description
Date diagnosed
Related hospitalization(s)/ surgery(s)
Physician
Atopic dermatitis
03/10/1999
No
Dr. Hutchins
Master Medication List
Edit
Drug Name
Started
Ended
Class
Dose
How Often
Hydrocortisone
03/21/99
Topical steroid
Sparingly to affected areas
bid
Background
Edit
Allergies/Drug Reactions
Iodine
Family History
Father-IDDM, Eczema
Exercise Habits
Other

FIG.5c

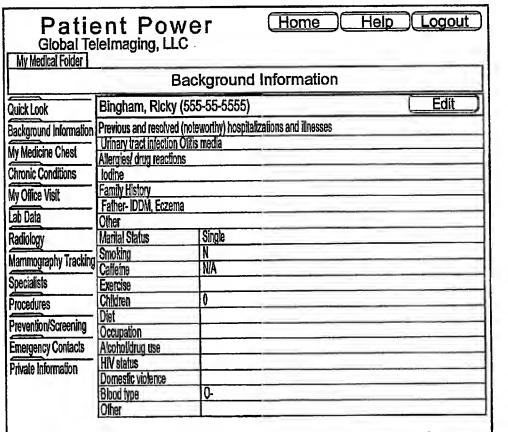

Patient Power
Global Telelmaging, LLC
Home
Help
Logout
My Medical Folder
Background Information
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Edit
Previous and resolved (noteworthy) hospitalizations and illnesses
Urinary tract infection Otitis media
Allergies/ drug reactions
Iodine
Family History
Father- IDDM, Eczema
Other
Marital Status
Single
Smoking
N
Caffeine
N/A
Exercise
Children
0
Diet
Occupation
Alcohol/drug use
HIV status
Domestic violence
Blood type
O-
Other

FIG.5d

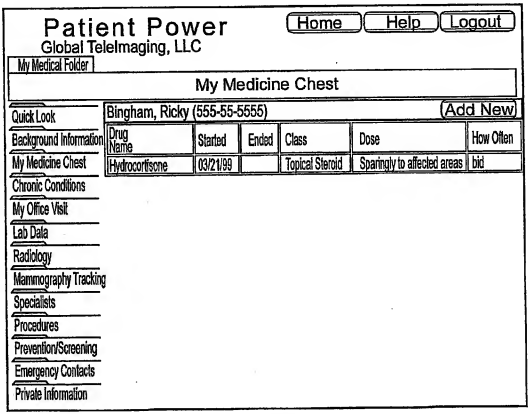

Patient Power
Global Telelmaging, LLC
Home
Help
Logout
My Medical Folder
My Medicine Chest
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Drug Name
Started
Ended
Class
Dose
How Often
Hydrocortisone
03/21/99
Topical Steroid
Sparingly to affected areas
bid

FIG.5e

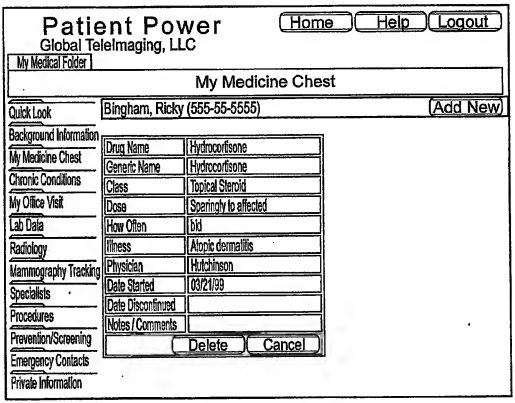

Patent Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
My Medicine Chest
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Drug Name
Hydrocortisone
Generic Name
Hydrocortisone
Class
Topical Steroid
Dose
Sparingly to effected
How Often
bid
Illness
Atopic dermatitis
Physician
Hutchinson
Date Started
03/21/99
Date Discontinued
Notes / Comments
Delete
Cancel

FIG.5f

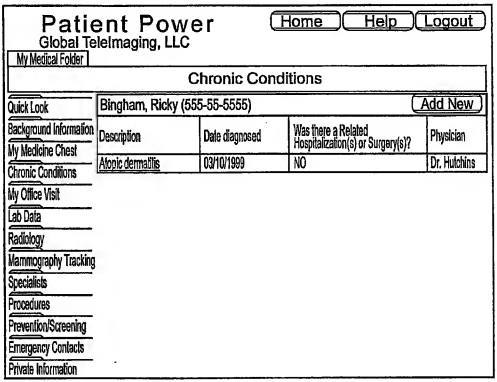

Patient Power
Global Telelmaging, LLC
Home
Help
Logout
My Medical Folder
Chronic Conditions
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Description
Date diagnosed
Was there a Related Hospitalization(s) or Surgery(s)?
Physician
Atopic dermatitis
03/10/1999
NO
Dr. Hutchins

FIG.5g

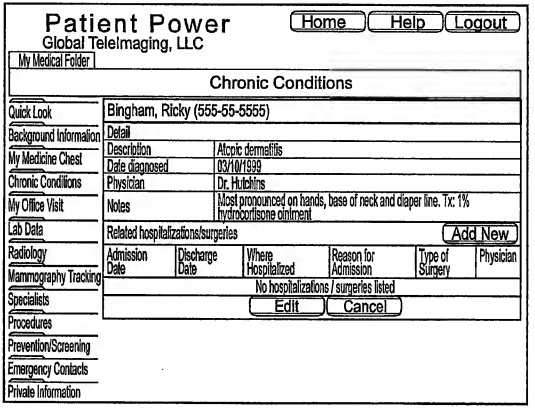

Patient Power
Global Telelmaging, LLC
Home
Help
Logout
My Medical Folder
Chronic Conditions
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Detail
Description
Atopic dermatitis
Date diagnosed
03/10/1999
Physician
Dr. Hutchins
Notes
Most pronounced on hands, base of neck and diaper line. Tx: 1% hydrocortisone ointment
Related hospitalizations/surgeries
Add New
Admission Date
Discharge Date
Where Hospitalized
Reason for Admission
Type of Surgery
Physician
No hospitalizations / surgeries listed
Edit
Cancel

FIG.5h

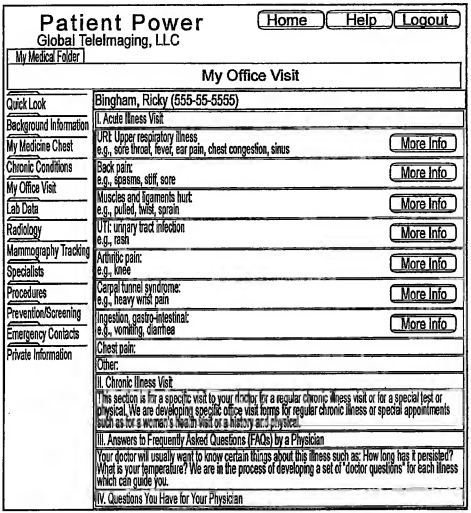

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
My Office Visit
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
I. Acute Illness Visit
URI: Upper respiratory illness
e.g., sore throat, fever, ear pain, chest congestion, sinus
More Info
Back pain:
e.g., spasms, stiff, sore
More Info
Muscles and ligaments hurt:
e.g., pulled, twist, sprain
More Info
UTI: urinary tract infection
e.g., rash
More Info
Arthritic pain:
e.g., knee
More Info
Carpal tunnel syndrome:
e.g., heavy wrist pain
More Info
Ingestion, gastro-intestinal:
e.g., vomiting, diarrhea
More Info
Chest pain:
Other:
II. Chronic Illness Visit
This section is for a specific visit to your doctor for a regular chronic illness visit or for a special test or physical. We are developing specific office visit forms for regular chronic illness or special appointments such as for a women's health visit or a history and physical.
III. Answers to Frequently Asked Questions (FAQs) by a Physician
Your doctor will usually want to know certain things about this illness such as: How long has it persisted? What is your temperature? We are in the process of developing a set of "doctor questions" for each illness which can guide you.
IV. Questions You Have for Your Physician

FIG.5i

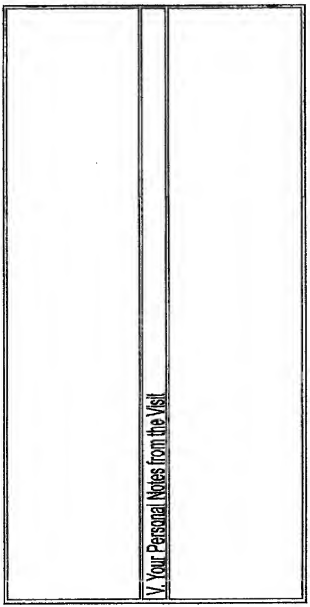


FIG.5j

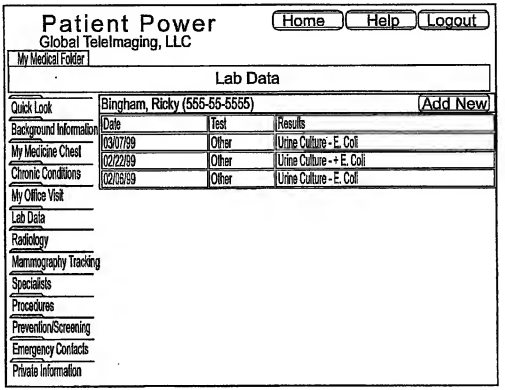

Patent Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Lab Data
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Date
Test
Results
03/07/99
Other
Urine Culture - E. Coli
02/22/99
Other
Urine Culture - + E. Coli
02/05/99
Other
Urine Culture - E. Coli

FIG.5k

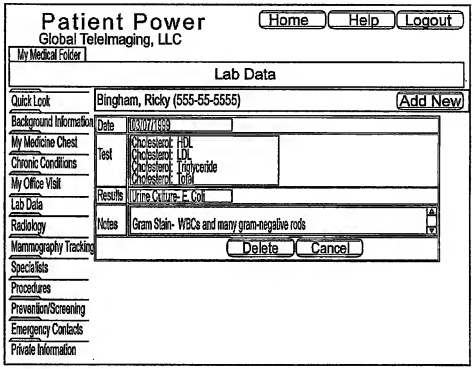

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Lab Data
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Date
10/30/7/1999
Test
Cholesterol: HDL
Cholesterol: LDL
Cholesterol: Triglyceride
Cholesterol: Total
Results
Urine Culture- E. Coli
Notes
Gram Stain- WBCs and many gram-negative rods
Delete
Cancel

FIG.5I

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Lab Data
Quick Look
Bingham, Ricky (555-55-5555)
Add New
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Date
10/07/97 1:00
Test
Cholesterol: HDL
Cholesterol: LDL
Cholesterol: Triglyceride
Cholesterol: Total
Results
Urine Culture-E. Coli
Notes
Urine Gram Stain- WBCs, many gram-negative rods
Delete
Cancel

FIG.5n

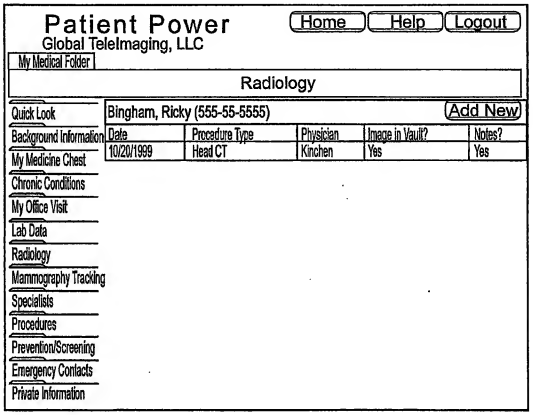

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Radiology
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Date
Procedure Type
Physician
Image in Vault?
Notes?
10/20/1999
Head CT
Kinchen
Yes
Yes

FIG.5o

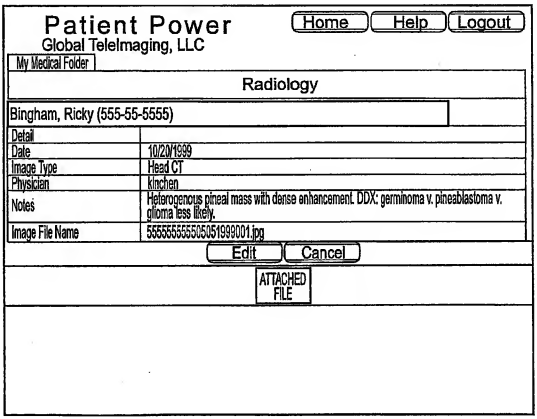

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Radiology
Bingham, Ricky (555-55-5555)
Detail
Date
10/20/1999
Image Type
Head CT
Physician
kinchen
Notes
Heterogeneous pineal mass with dense enhancement. DDX: germinoma v. pineablastoma v. glioma less likely.
Image File Name
55555555550505l999001.jpg
Edit
Cancel
ATTACHED FILE

FIG.5p

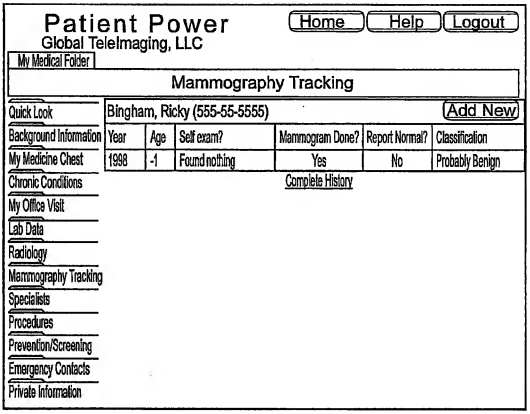

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Mammography Tracking
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Year
Age
Self exam?
Mammogram Done?
Report Normal?
Classification
1998
-1
Found nothing
Yes
No
Probably Benign
Complete History

FIG.5q

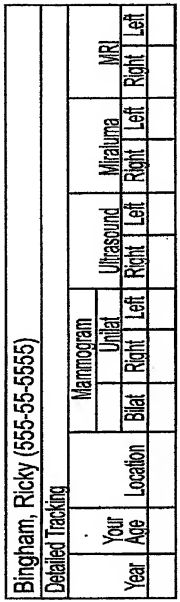

Bingham, Ricky (555-55-5555)
Detailed Tracking
Year
Your Age
Location
Mammogram
Bilat
Unilat
Right
Left
Ultrasound
Right
Left
Miraluma
Right
Left
MRI
Right
Left

FIG.5r

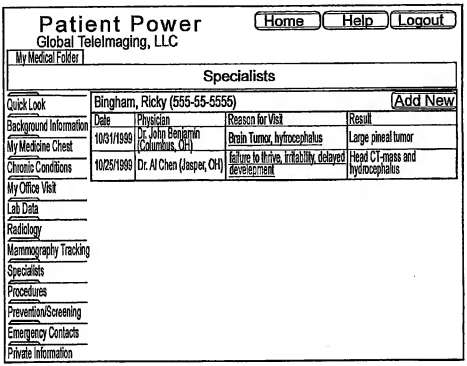

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Specialists
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Date
Physician
Reason for Visit
Result
10/31/1999
Dr. John Benjamin (Columbus, OH)
Brain Tumor, hydrocephalus
Large pineal tumor
10/25/1999
Dr. Al Chen (Jasper, OH)
failure to thrive, irritability, delayed development
Head CT-mass and hydrocephalus

FIG.5s

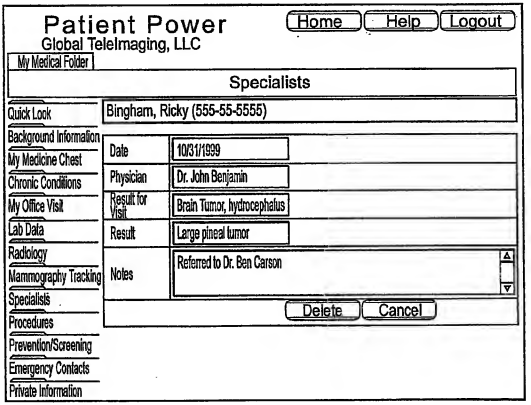

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Specialists
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Date
10/31/1999
Physician
Dr. John Benjamin
Result for Visit
Brain Tumor, hydrocephalus
Result
Large pineal tumor
Notes
Referred to Dr. Ben Carson
Delete
Cancel

FIG.5t

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Specialists
Quick Look
Bilngham, Ricky (555-55-5555)
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Date
10/25/1999
Physician
Dr. Al Chan (Jasper,
Result for Visit
Fatima to Imma,
Result
Head CT- mass and hy
Notes
Referral to Dr. Benjamin, Pediatric Oncologist
Delete
Cancel

FIG.5u

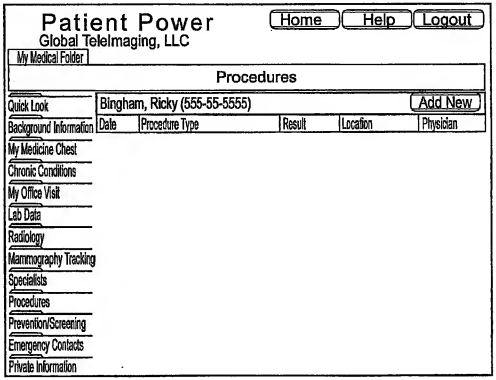

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Procedures
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Date
Procedure Type
Result
Location
Physician

FIG.5v

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Prevention/Screening
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Vaccine
Date
Criteria
Recall Date
Hep B Vax
11/07/1998
12/24/1998
Hep B Vax
06/12/1999
12/16/1999
Hep B Vax
12/10/1998
06/16/1999
Screening
Date
Criteria
Recall Date

FIG.5w

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Prevention/Screening
Quick Look
Bingham, Ricky (555-55-5555)
Background Information
Detail
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Vaccine/Screen
Screen: Authority
Screen: Blood Glucose
Screen: Blood Pressure
Screen: Cholesterol
Date
11/07/1996
Criteria
Recall Date
10/21/1998
Delete
Cancel

FIG.5x

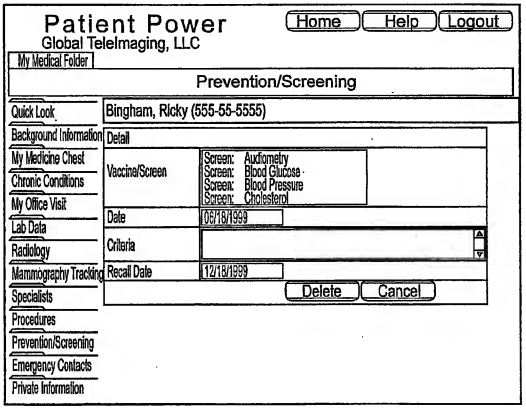

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Prevention/Screening
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Detail
Vaccine/Screen
Screen: Audiometry
Screen: Blood Glucose
Screen: Blood Pressure
Screen: Cholesterol
Date
05/18/1999
Criteria
Recall Date
12/18/1999
Delete
Cancel

FIG.5y

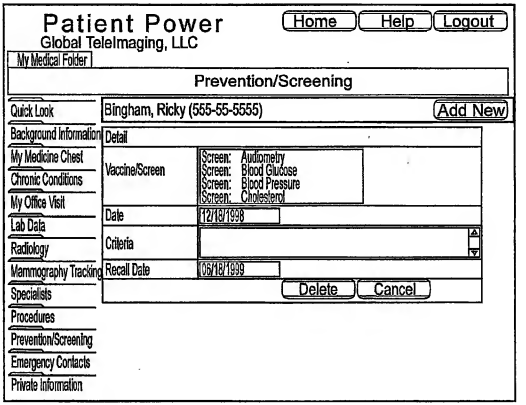

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Prevention/Screening
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Add New
Detail
Vaccine/Screen
Screen: Audiometry
Screen: Blood Glucose
Screen: Blood Pressure
Screen: Cholesterol
Date
12/19/1998
Criteria
Recall Date
06/18/1999
Delete
Cancel

FIG.5z

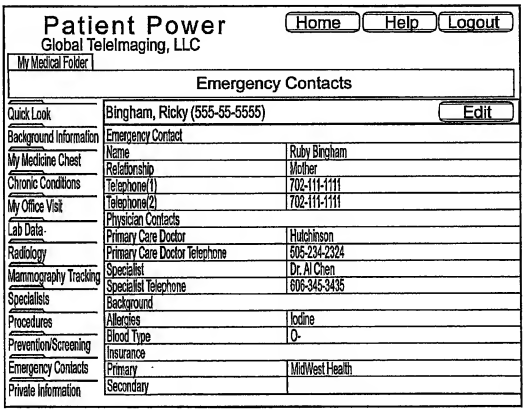

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Emergency Contacts
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)
Edit
Emergency Contact
Name
Ruby Bingham
Relationship
Mother
Telephone(1)
702-111-1111
Telephone(2)
702-111-1111
Physician Contacts
Primary Care Doctor
Hutchinson
Primary Care Doctor Telephone
505-234-2324
Specialist
Dr. Al Chen
Specialist Telephone
606-345-3435
Background
Allergies
Iodine
Blood Type
0-
Insurance
Primary
MidWest Health
Secondary

FIG.5aa

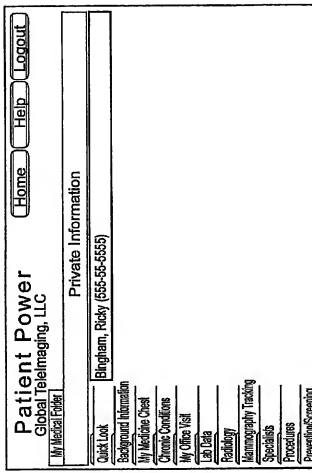

Patient Power
Global TeleImaging, LLC
Home
Help
Logout
My Medical Folder
Private Information
Quick Look
Background Information
My Medicine Chest
Chronic Conditions
My Office Visit
Lab Data
Radiology
Mammography Tracking
Specialists
Procedures
Prevention/Screening
Emergency Contacts
Private Information
Bingham, Ricky (555-55-5555)

FIG.5ab

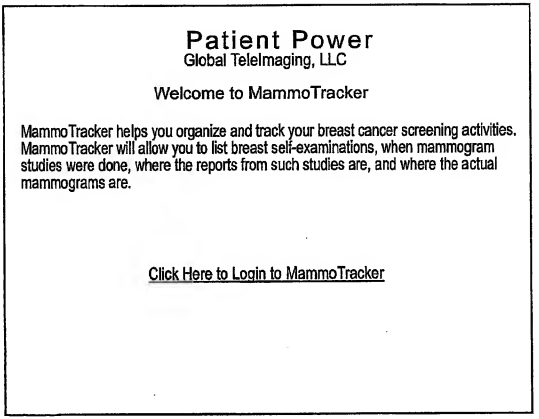

Patient Power
Global TeleImaging, LLC
Welcome to MammoTracker
MammoTracker helps you organize and track your breast cancer screening activities. MammoTracker will allow you to list breast self-examinations, when mammogram studies were done, where the reports from such studies are, and where the actual mammograms are.
Click Here to Login to MammoTracker

FIG.5ac

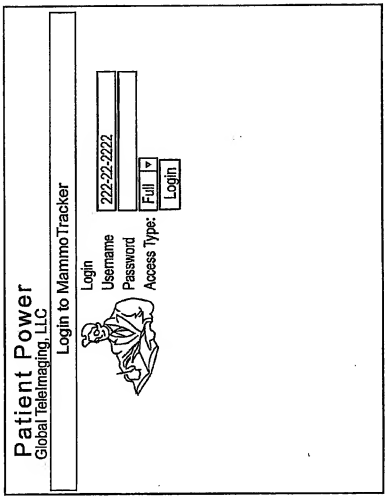

Patent Power
Global TeleImaging, LLC
Login to MammoTracker
Login
Username
Password
Access Type:
222-22-2222
Full
Login

FIG.5ad

Home | Help | Logout

Patient Power

Global TeleImaging, LLC

MammoTracker

Doe, Jane (222-22-2222) — Add New

Year	Age	Self-Exam?	Mammogram Done?	Report Normal?	Classification	Do You Have the Report in Your Possession?	Do You Know Where Actual Mammogram Is?	Do You Have a Copy of Actual Mammogram?
1994	34	Found Nothing	Yes	Yes	Benign	Yes	Yes	Yes
1995	35	Found something suspicious	Yes	Yes	Highly suggestive of malignancy	No	No	No
1995	35	Found something suspicious	Yes	No	Incomplete-need more information	No	Yes	No
1996	36	Found something suspicious	Yes	No	Probably benign	Yes	Yes	No
1997	37	Found something suspicious	No	No	Benign	No	No	No
1998	38	Found Nothing	No	No	Incomplete-need more information	No	No	No
1999	39	Found something suspicious	Yes	Yes	Benign	No	Yes	Yes

FIG.5ae

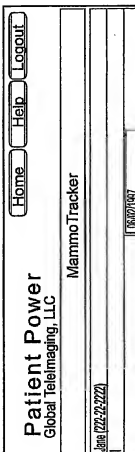

Patient Power
Global Telelmaging, LLC
Home
Help
Logout
MammoTracker
Doe, Jane (222-22-2222)
Detail
Date
06/02/1997
Self-Exam
Found something suspicious?
Mammogram Done?
No
Mammogram Report Normal?
No
Classification?
Benign
Do You Have Report In Your Possession?
No
Do You Know Where Actual Mammogram Is?
No
Do You Have a Copy of Actual Mammogram?
No
Notes
Had follow-up diagnostic study
Detailed Tracking
Mammogram
Ultrasound
Mirabama
MRI
Initial
Location
Bilat
Right
Left
Right
Left
Right
Left
Right
Left
Here
Update
Delete
Cancel

FIG.5af

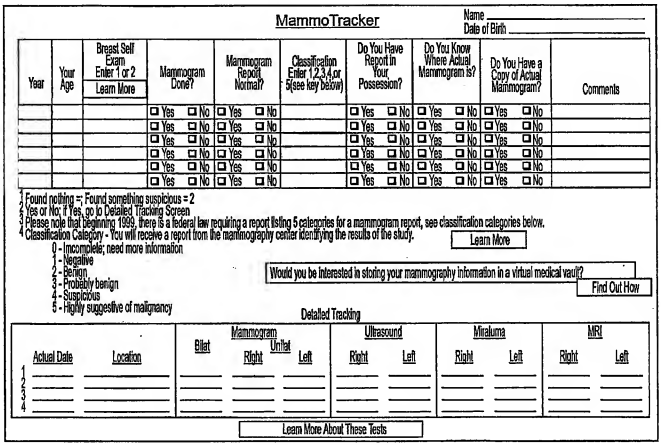

MammoTracker
Name
Date of Birth
Year
Your Age
Breast Self Exam Enter 1 or 2
Learn More
Mammogram Done?
Mammogram Report Normal?
Classification Enter 1,2,3,4,or 5(see key below)
Do You Have Report in Your Possession?
Do You Know Where Actual Mammogram Is?
Do You Have a Copy of Actual Mammogram?
Comments
☐ Yes ☐ No
1 Found nothing =; Found something suspicious = 2
2 Yes or No; if Yes, go to Detailed Tracking Screen
3 Please note that beginning 1999, there IS a federal law requiring a report listing 5 categories for a mammogram report, see classification categories below.
4 Classification Category - You will receive a report from the mammography center identifying the results of the study.
Learn More
0 - Incomplete; need more information
1 - Negative
2 - Benign
3 - Probably benign
4 - Suspicious
5 - Highly suggestive of malignancy
Would you be interested in storing your mammography information in a virtual medical vault?
Find Out How
Detailed Tracking
Actual Date
Location
Biliet
Mammogram
Right
Unilet
Left
Ultrasound
Right
Left
Miralama
Right
Left
MRI
Right
Left
1
2
3
4
Learn More About These Tests

FIG.5ag

Patent Power Flexible Spending Account Tracking ANNUAL FSA AMOUNT: $ 450.00

	Jan	...	Dec	TOTAL
Patient Power Purchases*	...			$ —
Medical not paid by insurance:		...		$ —
Prescription drugs/co-pay	$ 7.00	...		$ 35.00
Insurance deductibles		...		$ —
Physician visits/co-payments		...		$ 20.00
Dental not paid by insurance:		...		$ —
Vision not paid by insurance:		...		$ —
Contact lenses/supplies		...	$ 165.00	$ 324.60
Prescription sunglasses		...		$ —
Monthly Total	$ 7.00	...	$ 165.00	$ 379.60
Annual Sub-Total	$ 7.00	...	$ 379.00	$ 379.60
Amount of Reimbursement		...		
Amount Paid		...		
Remaining Unallocated Funds	$ 7.00	...	$ 379.00	

Amount Remaining (to be used before the Plan Year end): $ 70.40

FIG.5ah

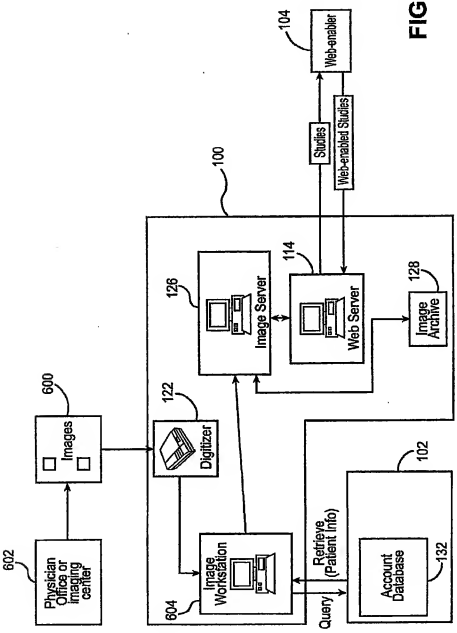

Physician Office or Imaging center
602
Images
600
Digitizer
122
Image Workstation
604
Image Server
126
Web Server
114
Image Archive
128
Studies
Web-enabled Studies
Web-enabler
104
100
Retrieve (Patient Info)
Query
Account Database
132
102

FIG.6

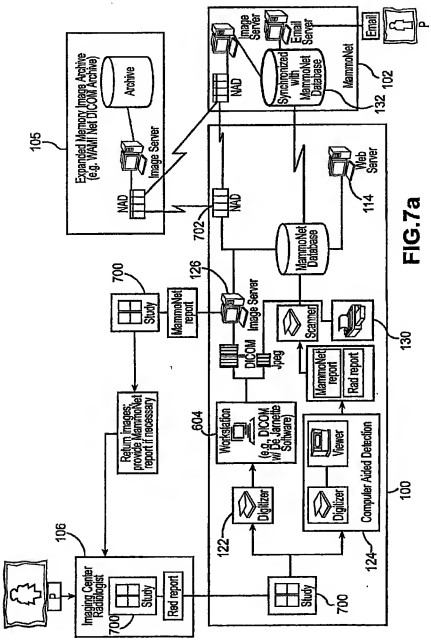

Expanded Memory Image Archive (e.g. WAM! Net DICOM Archive)
Archive
Image Server
NAD
105
Image Server
Email Server
Email
Synchronized with MammoNet Database
MammoNet
132
102
NAD
Web Server
114
MammoNet Database
702
700
Study
MammoNet report
126
Image Server
Scanner
130
DICOM
Jpeg
MammoNet report
Read report
Return Images; provide MammoNet report if necessary
604
Workstation (e.g. DICOM w/ PS Jamette Software)
Digitizer
Viewer
Computer Aided Detection
100
122
124
106
Imaging Center Radiologist
Study
Read report
700
Study
700

FIG.7a

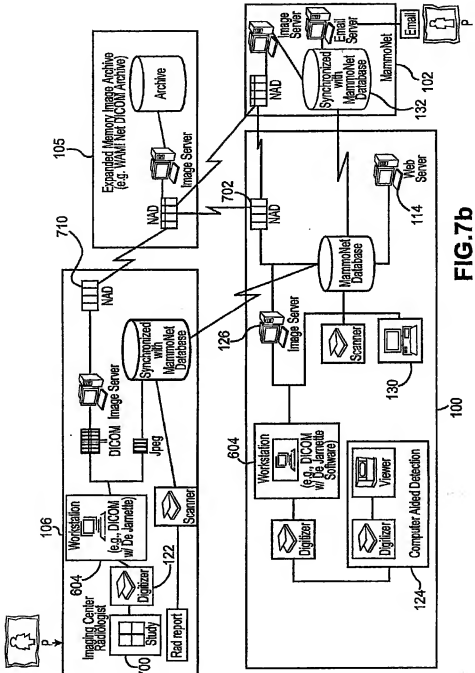

Expanded Memory Image Archive (e.g. WAM! Net DICOM Archive)
Archive
Image Server
NAD
105
710
NAD
Synchronized with MammoNet Database
DICOM
Image Server
Jpeg
Scanner
106
Workstation (e.g., DICOM w/ De Jarnette)
Digitizer
122
604
Imaging Center Radiologist
Study
Rad report
700
P
126
702
NAD
Image Server
Scanner
Workstation
DICOM w/ De Jarnette Software
Digitizer
Viewer
Digitizer
Computer Aided Detection
124
130
604
100
MammoNet Database
Web Server
114
NAD
Image Server
Email Server
Synchronized with MammoNet Database
MammoNet
132
102
Email
P

FIG.7b

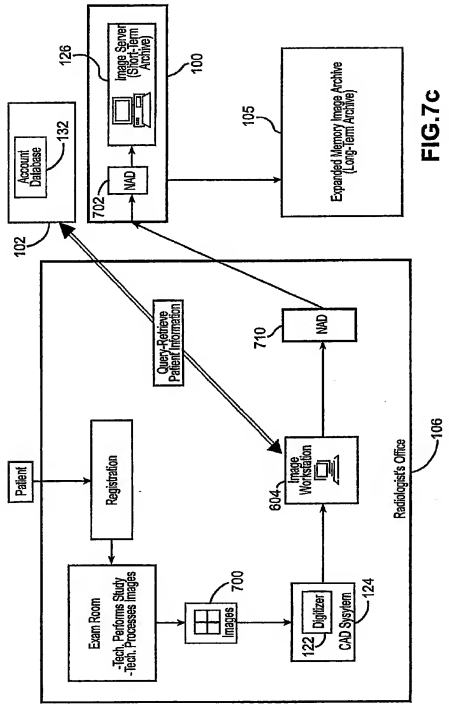

Patient
Registration
Exam Room
-Tech. Performs Study
-Tech. Processes Images
Images
700
122
Digitizer
CAD System
124
Image Workstation
604
Radiologist's Office
106
NAD
710
Query-Retrieve Patient Information
102
Account Database
132
126
Image Server (Short-Term Archive)
NAD
702
100
105
Expanded Memory Image Archive (Long-Term Archive)

FIG.7c

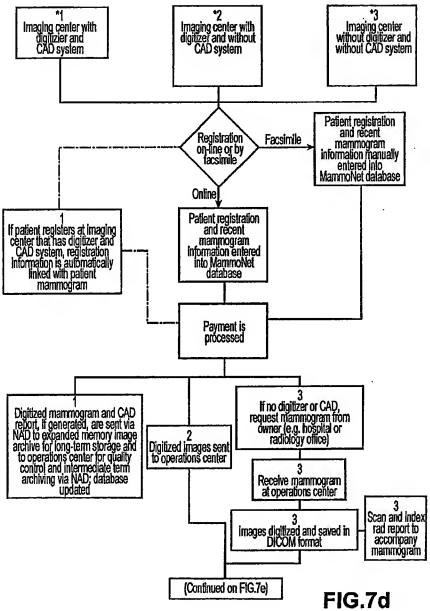

*1
Imaging center with digitizer and CAD system
*2
Imaging center with digitizer and without CAD system
*3
Imaging center without digitizer and without CAD system
Registration on-line or by facsimile
Facsimile
Patient registration and recent mammogram information manually entered into MammoNet database
Online
1
If patient registers at imaging center that has digitizer and CAD system, registration information is automatically linked with patient mammogram
Patient registration and recent mammogram information entered into MammoNet database
Payment is processed
1
Digitized mammogram and CAD report, if generated, are sent via NAD to expanded memory image archive for long-term storage and to operations center for quality control and intermediate term archiving via NAD; database updated
2
Digitized images sent to operations center
3
If no digitizer or CAD, request mammogram from owner (e.g. hospital or radiology office)
3
Receive mammogram at operations center
3
Images digitized and saved in DICOM format
3
Scan and index rad report to accompany mammogram
(Continued on FIG.7e)

FIG.7d

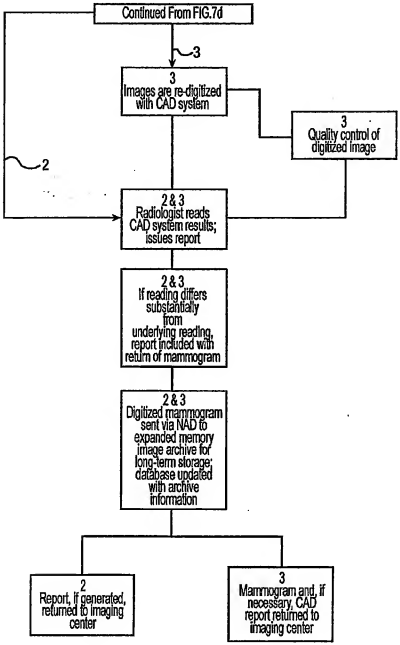

Continued From FIG.7d
3
3
Images are re-digitized with CAD system
3
Quality control of digitized image
2
2 & 3
Radiologist reads CAD system results; issues report
2 & 3
If reading differs substantially from underlying reading, report included with return of mammogram
2 & 3
Digitized mammogram sent via NAD to expanded mammo image archive for long-term storage; database updated with archive information
2
Report, if generated, returned to imaging center
3
Mammogram and, if necessary, CAD report returned to imaging center

FIG.7e

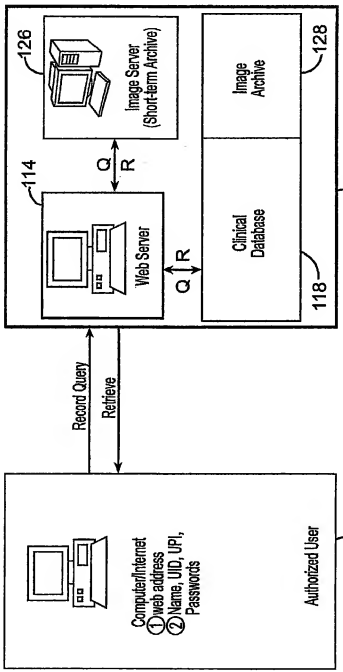

Computer/Internet
1 web address
2 Name, UID, UPI, Passwords
Authorized User
111
Record Query
Retrieve
Web Server
114
Q
R
Image Server (Short-term Archive)
126
Clinical Database
118
Image Archive
128
100

FIG.8a

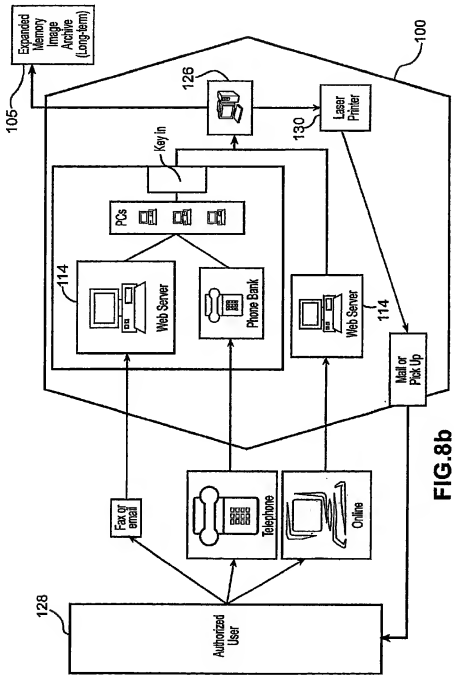

Expanded Memory Image Archive (Long-term)
105
100
126
Laser Printer
130
Key In
PCs
114
Web Server
Phone Bank
Web Server
114
Mail or Pick Up
Fax or email
Telephone
Online
128
Authorized User

FIG.8b

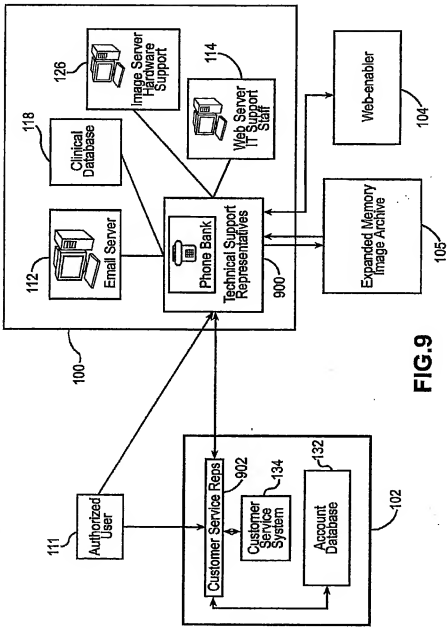


Image Server Hardware Support
126
Web Server IT Support Staff
114
Clinical Database
118
Email Server
112
Phone Bank
Technical Support Representatives
900
Web-enabler
104
Expanded Memory Image Archive
105
100
Authorized User
111
Customer Service Reps
902
Customer Service System
134
Account Database
132
102

FIG.9

METHOD AND SYSTEM FOR MANAGING PATIENT MEDICAL RECORDS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/181,215, filed Feb. 9, 2000, which is hereby incorporated by reference in its entirety.

BACKGROUND

[0002] 1. Field of the Invention

[0003] The present invention broadly relates to the field of electronic commerce, telemedicine, and global network medical record management services. More particularly, the present invention relates to a system and method for creating, storing, accessing, and distributing focused patient medical records.

[0004] 2. Background of the Invention

[0005] A focused medical record is the cornerstone of comprehensive and effective health care. The medical record facilitates patient care by documenting a patient's baseline and providing physicians with the clinical data necessary to detect and successfully treat medical problems in the early stages of development. Often, having a focused medical record that presents a clear and thorough medical history is the difference between recovery and death.

[0006] Among health care professionals, a medical record is commonly defined as a repository for information and data collected from a patient's encounter with the health care system. Typically, the structure of the medical record follows a problem-oriented approach, in which each piece of information or data is associated with some specific problem. In addition, a typical medical record is ambulatory, such that ongoing records are appended and updated across multiple visits and treatments. The content of the medical records takes a variety of forms, from handwritten physician notes to diagnostic images such as x-rays and CT (computer tomography) scans.

[0007] For the most part, medical records are stored in traditional paper-based formats. The physician maintains a chart on each patient and the patient has individual charts at each of her physicians, e.g., primary care physician, specialists, and sub-specialists. Each chart contains documents such as check-up summaries, vaccinations charts, sick visit summaries, laboratory results, x-ray reports, and prescriptions. Unless a particular medical problem requires the collective care of several physicians and correspondence between them, a patient's charts at individual physicians are rarely integrated and, typically, no one chart contains all of the medical information of the patient. In addition to this lack of integration, the paper-based records also suffer from missing, illegible, redundant, and inaccurate content; unstructured, disorganized, and improperly sorted information; and inefficient access, availability, and retrieval.

[0008] To some extent, the application of computer technology to medical record maintenance has alleviated some of the disadvantages associated with paper-based records. Electronic medical records (EMRs) digitally store the information found in traditional paper-based records. Other terms synonymous with EMR are computerized medical records (CMRs) and computer-based patient records (CPRs). As used herein, the term "patient medical record" (PMR) covers these electronic records (EMR, CMR, and CPR) as well as paper-based records. Inherently, these computerized records are more organized, accurate, and accessible in comparison to paper-based records. In addition, the computerized records have the potential to accommodate a greater variety of record media, such as medical imaging and videography.

[0009] Counteracting the positive strides made by computer technology, the rise of managed care has often hindered the overall management of medical records. Ironically, in efforts to contain costs, health insurance companies have opted for managed care provided by health maintenance organizations (HMOs), which often restrict access to practitioners. Such restrictions have alienated physicians and patients, resulting in frequent changes in health plans by both physicians and patients. Patients are often directed to physicians who do not have the patient's prior records. Consequently, health care has become increasingly disjointed, making long term physician-patient relationships something of a rarity.

[0010] Unquestionably, electronic medical records have simplified the acquisition of and condensed the storage of patient data. However, in the face of multiple health care providers, health care insurance companies, and their corresponding individual computer medical record systems, the EMRs fail to provide centralized and integrated records management. A single patient's EMR is typically fragmented between different health care providers and health insurance providers, with records distributed across multiple repositories. As a result, a physician does not have an integrated view of the patient data, and consequently lacks the comprehensive medical history necessary for efficient and accurate diagnosis and treatment. In addition to decentralized records, conventional EMRs are usually text-based with limited and inconsistent means of storing clinical images. Thus, not only is the patient's medical data strewn across multiple computer systems, but the physical charts and diagnostic-quality images (on paper) are stored in separate locations.

[0011] Recognizing the drawbacks to paper-based medical records and decentralized EMRs, many healthcare institutions and private medical record companies have turned to Internet-based medical record management systems. In fact, commentators largely agree that the future patient record will be a computer-based, multimedia record capable of including free text, high-resolution images, sound, full motion video and elaborate coding schemes, accessible from anywhere around the world. The industry that is cultivating this vision is referred to as telemedicine.

[0012] Telemedicine is the use of computers, the Internet, and other communication technologies to provide medical care to patients at a distance. Early forms of this technology involved a simple intranet connection between a hospital and the home of a doctor to facilitate immediate preliminary diagnoses and initial courses of treatment for critical patients brought into the hospital. Later generations of telemedicine incorporated the Internet as a means for distributing medical records to specialists throughout the world for quick and convenient medical referrals. The latest iteration of telemedicine stores medical records and images such as x-rays on the Internet, for access and assessment by physicians such as radiologists. However, this practice of reviewing medical images online, referred to as teleradiology, is gen-

erally limited to preliminary "reads" to determine if further investigation is required, and is not suitable for full diagnoses.

[0013] Each of these telemedicine approaches focuses on the physician's control and use of the medical records, without regard to the patient's access. In fact, as with all medical records, electronic records are proprietary and their contents are owned by the provider producing the images, such as a hospital, clinic, HMO, or practitioner's office. Thus, compounding the problem of fragmented patient records, patients have no ownership control with which to consolidate the records. Without a personal stake, physicians rarely take the initiative to gather and integrate all records from various physician offices and facilities such as hospitals. In addition, even if a patient is willing to gather and consolidate the large volume of records, the patient lacks the medical knowledge necessary to create a focused patient medical record that contains only the information most relevant to future medical diagnoses and actual care. Thus, frequently the physician directs the patient's medical care without a full knowledge of the patient's medical history, and the patient, without control of the records, has little opportunity to give the physician a complete picture of the medical history.

[0014] In an attempt to provide patients with greater control over their medical records, several PMR services provide Internet websites in which to store, update, and retrieve patient medical records. Some of the websites provide medical data management as a primary function while others provide the service as a part of a larger health website. Examples of these websites include epicsys.com™, abaton.com™, medscape.com™, medicalrecord.com™, medbroadcast.com™, TheHealthNetwork.com™, 4healthylife.com™, healthmagic.com™, personalmd.com™, wellmed.com™, webmd.com™, aboutmyhealth.net™, and vistalink.com™. While some websites, such as epicsys.com™ and abaton.com™, provide PMR services for health groups (e.g., health administrators, clinicians, and hospitals), the remaining websites, as well as the present invention, target the consumer, or patient, and give the patient ownership and control of the medical records.

[0015] The websites providing PMR services to patient consumers share one or more of the following functions: 1) provide website features and structured tabs that emulate paper-based medical charts; 2) give the patient control of the creation, maintenance, and distribution of medical records; 3) store laboratory results, specialist reports, and EKG (electrocardiogram) copies; 4) match physicians of a participating primary physicians network to patients in need of medical advice and treatment; 5) provide patient consumers with technical advice concerning creation of medical records and use of website features; 6) enable physicians to view and update medical records with permission of the patient; and 7) provide key information for emergency situations.

[0016] In addition to these typical functions, one website, vistalink.com™, offers the expanded capability of storing images such as x-rays, digitized x-rays, magnetic resonance imaging (MRIs), CT scans, and ultra-sounds. However, as especially relevant to the present invention, these digital images do not attain the quality required for accurate diagnosis. For example, vistalink.com™ offers one megabyte of storage and suggests that an x-ray JPEG image of 42 kilobytes is sufficient for assessment by a physician. However, true diagnostic x-rays require on the order of 32 megabytes of uncompressed storage or 4 megabytes of compressed storage. In addition, as another example, a full mammography x-ray series, which is required for an accurate diagnosis, requires on the order of 168 megabytes of storage. Thus, none of the current PMR services provide diagnostic-quality medical imaging.

[0017] In addition to inadequate image capability, the prior art web-based PMR services suffer from several more significant shortcomings. First, although the websites give patients control of medical records, no website appears to facilitate an interactive exchange between a patient and primary care physician. Although some websites enable physicians to view and update records, none use an interactive exchange to allow the physician to act as a patient care coordinator of key medical information. In light of the voluminous records associated with the typical patient, these websites lack the physician guidance necessary for patients to determine which records should be included in a focused patient medical record. In other words, the prior art websites fail to facilitate a partnership between patient and physician that creates, maintains, and uses a completely integrated and focused medical record to assess and monitor the patient's health and to take appropriate action.

[0018] Second, web-based PMR services provide limited means of conveying key medical information in emergency situations. As noted above, most services provide a summary of critical medical information through website postings. Typically, in an emergency, the patient herself or a user card on the patient gives the medical professional the patient's account access information. The medical professional must then log on to the Internet, locate the appropriate website, traverse the access steps (e.g., username and patient identification), and view the critical information. Although the medical professional eventually does receive the critical information, frequently in emergencies it is received too late. Therefore, plainly stated, the prior art web-based PMR services lack an immediate means of communicating critical medical data.

[0019] Third, the prior art web-based PMR services fail to meet the specific needs of routine mammography studies. Specifically, the prior art websites lack the ability to store, retrieve, and transmit a series of diagnostic-quality mammograms that are owned and controlled by the patient. Mammography is the only diagnostic procedure proven to save lives by early detection of breast cancer. American Cancer Society guidelines recommend that women over the age of 40 undergo annual mammography. After an initial baseline image, each annual mammogram documents any gradual changes. Therefore, having a consistent series of regular mammograms is crucial to identifying suspicious areas and prescribing early intervention. In addition, accurate identification of problems, by medical professionals and computer-aided detection (CAD), relies on the original mammograms or copies of equal diagnostic quality. As discussed above, the prior art websites do not provide this quality.

[0020] In addition to inferior quality, the prior art website lack procedures for acquiring the routine mammogram, storing diagnostic-quality mammograms in a central location, and retrieving and transmitting the images for evaluation by remote medical specialists.

SUMMARY OF THE INVENTION

[0021] The present invention, referred to herein as Patient Power™, is a method and system for creating, storing, accessing, updating, and distributing patient medical records, especially diagnostic-quality medical imaging, under the control of a patient and the coordinated care of the patient and physician. Broadly stated, the present invention provides centralized and focused online medical record storage, facilitates a patient-physician partnership by which to create and maintain the focused online medical records, provides means for obtaining and storing diagnostic-quality images, establishes Internet-based communication through which to transmit medical records, provides immediate means for conveying critical medical information in emergency situations, and provides means for storing, receiving, and transmitting diagnostic-quality mammograms.

[0022] According to a representative embodiment, the components of the present invention are a scanner, a clinical database, an account database, a digitizer, an e-mail server, an image server with an image archive, a web server, an Internet service provider (ISP), a web-enabler, an expanded memory image archive, and a series of Internet-based software applications and graphical user interfaces (GUIs) that give the patients and physicians access to view and manipulate the information in the clinical database and image archives.

[0023] The scanner, which could be a facsimile machine, digitally encodes images of paper documents, such as EKGs, into computer files that are capable of creating legible or readable images, but not necessarily diagnostic-quality images. The clinical database stores scanned documents, such as EKGs and special reports, and textual information that are entered directly into a computer. The account database stores the contact, demographic, and financial information associated with each patient, such as name, address, phone number, social security number, and date of birth. The digitizer digitally encodes medical images, especially radiological images such as x-rays, into computer files capable of producing diagnostic-quality images on computer monitors. The image server receives the digitally encoded medical images from the digitizer and transmits them either to the image archive or the expanded memory image archive for storage, or to remote computer terminals for display and analysis. Finally, the e-mail server, the web server, the web-enabler, the GUIs, and the ISP facilitate web-based communication, including the transmission of medical records.

[0024] In the preferred embodiment of the present invention, monetary incentives encourage a network of participating physicians, preferably primary care physicians and radiologists, to assist patients in creating a medical record that is streamlined and focused, containing only the information most relevant to current health conditions and future diagnoses and care. The present invention pays primary physicians for approximately 2 to 3 short consultations a year (during regular office visits), aimed at deciding what data should be included in and excluded from a patient's medical record. For example, if a patient mistakenly omits a chronic condition such as a diabetic ulcer, the physician would direct the patient to include it in the medical record. As another example, if a patient recently underwent heart bypass surgery that produced hundreds of documents, the physician would summarize the event for entry into the medical record. Under the physician's guidance, the patient enters the data into the medical record and owns and controls the entire medical record. In the end, the patient owns a focused medical record that enables the primary physician and other specialists to make efficient medical assessments based on concise medical records.

[0025] As the owner of the medical record, the patient has the option of giving a doctor access to view and update the information. In this manner, the present invention allows a patient to work with her primary physician in maintaining a focused medical record. A direct benefit of this partnership is that the primary physician is aware of all critical medical data at all times, and as a result, can make informed accurate medical decisions, and can more efficiently direct the overall health care of the patient.

[0026] In the preferred embodiment of the present invention, a patient first registers with a system operator for the service, providing basic background information, such as address, occupation, and age. This registration can occur by facsimile correspondence (e.g., from a doctor's office) or by online interaction through a series of registration GUIs (e.g., from the patient's home). Alternatively, a patient can register by calling a telephone call center, which is staffed by nurses or other healthcare professionals. The telephone call center could also use an interactive voice response (IVR) unit for registration. Once registered, the system operator gives the patient a username and unique patient identifier (UPI), establishes an account under the patient's name in the account database, and creates a file in the clinical database, ready to accept medical record information.

[0027] Once the patient is registered, the present invention provides means for entering data into the patient's medical record. The data is in three primary forms: 1) textual records; 2) scanned records, such as EKGs and special reports; and 3) medical images, such as x-rays. With guidance from the patient-physician partnership described above, an authorized user, who may be, for example, the patient, a relative of the patient, or the patient's physician, enters textual information through an online Internet connection that interfaces with the GUIs and the web server. The web server stores in the clinical database the textual data received through the GUIs. For scanned records, the scanner (or a facsimile machine) digitally encodes the original documents and stores the encoded files in the clinical database. For medical images, which require diagnostic quality (significantly higher than the quality required for the scanned documents), the digitizer digitally encodes an original medical image in a high-resolution format file. The image server receives the file and transmits the file to the archives for storage.

[0028] With the data entered into the medical record, the present invention further provides means to retrieve and transmit the medical data. A user with authorized access to the medical record (e.g., the patient or her relative or primary physician) interfaces through an online Internet connection with the GUIs provisioned on the web server. The GUIs prompt the user to initiate a query to the web server for the desired medical record. If the desired record is a textual document or a scanned document, the web server consults the clinical database, retrieves the record, and transmits it back to the user. If the desired record is a

diagnostic-quality image, then the web server queries the image server to retrieve the diagnostic-quality image from the archives. The image server returns the medical record to the web server and the web server transmits the record back to the user. If the size of the digitally encoded file for the diagnostic-quality image is too large for efficient Internet transmission or the user does not have hardware capable of supporting diagnostic-quality resolution, the present invention also provides means for printing a hard copy of the image (e.g., a laser printer) and returning the hard copy to the user by conventional means, e.g., U.S. Mail. For each of these record retrieval methods, the present invention can return the record to the user or to a destination chosen by the user (e.g., a distant medical specialist for a referral or second opinion).

[0029] By enabling the storage and management of diagnostic-quality images, the present invention meets the specific needs of routine mammography studies. To further meet these needs, the present invention uses the GUIs to establish special records for tracking the routine mammograms. In addition, the present invention incorporates computer-aided detection to improve the accuracy in detecting early signs of disease.

[0030] Another important aspect of the present invention is the provision of an immediate means for communicating critical medical data. Once the patient has entered the medical data, the present invention marks the information most critical for an emergency situation. A single, concise GUI displays this critical information. Further, as an advantage over the prior art, the present invention provides a Patient Power Emergency Room Carrier (PERC) that stores the critical information in a portable form. In this manner, the patient carries the PERC at all times, e.g., the PERC would be stored in a memory card, such as a smart card, a flash card, a compact flash card, or a personal information carrier (PIC), which could be attached to a key chain or other device. The card is compatible with hospital computer terminals, e.g., using PCMCIA interfaces provisioned at each hospital. Thus, instead of requiring the emergency room staff to log onto the Internet and access the critical information page, the PERC enables instant plug-in and display capability. In addition, in an alternate embodiment, the memory card includes a patient's entire medical record that appears behind the critical information. This memory card, containing a total patient record, is referred to herein as Super PERC (Patient Power Electronic Record Carrier).

[0031] As a side note, it should be recognized that the term "computers" as used herein is intended to have the broadest possible meaning to encompass a portion of a computer, a single computer, or one or more computers in communication with each other. Indeed, one of the principal advantages of the present invention is that it can be implemented on any variety of computer network systems.

[0032] Accordingly, an object of the present invention is to provide a convenient, efficient medical data acquisition, management storage, and retrieval network.

[0033] Another object of the present invention is to create a network of participating primary physicians and radiologists.

[0034] Another object of the present invention is to give health consumers more control over their own medical care.

[0035] Another object of the present invention is to provide a PMR service to consumers who travel frequently, who have or are susceptible to chronic illnesses, and who need to centralize key medical data.

[0036] Another object of the present invention is to provide procurement, storage, and management of mammogram records for women who undergo mammography, to insure the availability and security of their mammograms and the capability of identifying breast abnormalities by computer-aided detection.

[0037] Another object of the present invention is to give each subscriber control over her medical information by providing the subscriber and her physicians with immediate and continuous access to that subscriber's relevant current medical information and past medical history, to enable that individual to receive the most efficient and appropriate medical care.

[0038] Another object of the present invention is to enhance the relationships between each subscriber and her physicians, by allowing them to work together to keep the critical information necessary for optimum medical care current and accessible.

[0039] Another object of the present invention is to provide a safe, permanent digital storage system for a woman's mammograms and for the patient's other significant medical images (X-rays, other radiological examinations), which can be conveniently retrieved and forwarded to the subscriber or her designated medical professional in a timely manner.

[0040] Another object of the present invention is to improve the quality, accuracy, and efficiency of a health care system.

[0041] Another object of the present invention is to lower health care costs by reducing the number of unnecessary hospital admissions and minimizing the duplication of diagnostic tests and procedures.

[0042] Another object of the present invention is to empower patients, permitting them to become more knowledgeable health care consumers and to better control their health care.

[0043] Another object of the present invention is to eliminate the considerable anxiety and unnecessary procedures, including surgical intervention, created by lost or unavailable mammographic studies.

[0044] Another object of the present invention is to allow for the use of computer-aided detection to further evaluate a mammogram.

[0045] Another object of the present invention is to create a simple and reliable mechanism for permitting transmittal of mammograms for second opinions or additional evaluation.

[0046] Another object of the present invention is to give women control of their mammograms and mammography reports.

[0047] As described herein, the present invention comprises a system and method that includes at least the following significant features:

[0048] 1) a digitizing procedure that obtains diagnostic-quality medical imaging for storage in a patient's medical record;

[0049] 2) a clinical database that stores textual and scanned documents;

[0050] 3) image archives that store diagnostic-quality images;

[0051] 4) a process for managing patient medical records that gives the patient ownership and control of the records, forms a partnership between physician and patient that promotes coordinated care, and provides incentives for the physician to assist the patient in creating a streamlined, focused medical record;

[0052] 5) a portable medical data storage that immediately communicates critical medical data for emergency situations (PERC);

[0053] 6) a portable medical data storage that contains most or all of a patient's medical record (Super PERC);

[0054] 7) a unique patient identifier; and

[0055] 8) a process for managing routine mammography studies.

[0056] These and other objects and advantages of the present invention are described in greater detail in the detailed description of the invention, the appended drawings, and the claims. Additional features and advantages of the invention will be set forth in the description that follows, will be apparent from the description, or may be learned by practicing the invention.

DESCRIPTION OF THE DRAWINGS

[0057] **FIG. 1** is a schematic diagram of the system architecture of the present invention.

[0058] **FIG. 2***a* is a preferred site map of the present invention.

[0059] **FIG. 2***b* is an image of the preferred website home page of the present invention.

[0060] **FIGS. 2***c*-**2***f* are images of screens giving contact information and company information about the medical record management service provider.

[0061] **FIG. 2***g* is an image of a "help" screen.

[0062] **FIG. 2***h* is a chart listing the structured tabs presented on the My Medical Folder, Global-ER, MammoTracker, and MammoNet screens.

[0063] **FIG. 3***a* is a schematic diagram illustrating patient account registration.

[0064] **FIGS. 3***b*-**3***i* are images of screens that the system displays during patient account registration.

[0065] **FIG. 4** is a schematic diagram illustrating the method by which medical records are entered into the patient medical record service.

[0066] **FIGS. 5***a*-**5***h* are images of the various screens that the system provides to a patient during entry of textual and scanned documents.

[0067] **FIG. 6** is a schematic diagram illustrating the entry of diagnostic-quality non-mammography images.

[0068] **FIGS. 7***a*-**7***c* are schematic diagrams illustrating the entry of diagnostic-quality mammography images.

[0069] **FIGS. 7***d* and **7***e* are a flowchart outlining the general workflow of the acquiring mammograms and storing them in patient medical records.

[0070] **FIGS. 8***a* and **8***b* are schematic diagrams illustrating the methods by which the present invention retrieves medical records.

[0071] **FIG. 9** is a schematic diagram illustrating the customer service and technical support provided by the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0072] The present invention, sometimes referred to herein as Patient Power™, is a system and method for providing web-based medical record management for patients. As an overview of the present invention, the following discussion describes the architecture and components of the system, and the business procedures and website operation that registers, establishes, and manages patient medical record accounts. This description of a system architecture and a method for implementing a medical record management service within that architecture are examples of preferred embodiments of the present invention. While the method described herein and illustrated in the figures contains many specific examples of information flow steps, these steps should not be construed as limitations on the scope of the invention, but rather as examples of information flow steps that could be used to practice the invention. As would be apparent to one of ordinary skill in the art, many other variations on the system operation are possible, including differently grouped and ordered method steps. Accordingly, the scope of the invention should be determined not by the embodiments illustrated in these examples, but by the appended claims and their equivalents.

[0073] System Architecture

[0074] Referring to **FIG. 1**, the present invention uses the Internet **99** to link together an operations center **100**, an administrative center **102**, a web-enabler **104**, an expanded memory image archive **105**, a plurality of primary physicians **106**, a plurality of referral physicians **108**, and a plurality of patients **110**. Operations center **100** provides all of the technical support, quality assurance, and backroom services required to support the features of the present invention. To meet these needs, operations center **100** includes an e-mail server **112**, a web server **114**, an Internet service provide (ISP) **116**, a scanner **117**, a clinical database **118**, a technical support system **120**, a digitizer **122**, a computer-aided detection (CAD) system **124**, an image server **126**, an image archive **128**, and a laser printer **130**.

[0075] E-mail server **112**, web server **114**, and ISP **116** interface with Internet **99** and enable web communication among operations center **100**, administrative center **102**, web-enabler **104**, expanded memory image archive **105**, the plurality of primary physicians **106**, the plurality of referral physicians **108**, and the plurality of patients **110**. Clinical database **118** stores medical data and scanned document files in separate accounts for each patient. Technical support system **120** provides assistance to users of the system

concerning hardware, software, website interface, file transfers, e-mail, and other technical problems.

[0076] Scanner 117, which could be a facsimile machine, digitally encodes images of paper documents into computer files that are capable of creating legible or readable images, but not necessarily diagnostic-quality images. Digitizer 122 digitally encodes original medical images into computer files capable of reproducing diagnostic-quality images.

[0077] CAD system 124 supplements radiological studies by digitally analyzing images for indications of disease and marking such indications for further analysis by, for example, an interpreting radiologist. Image server 126 receives the digitally encoded files from digitizer 122 and CAD system 124, and transmits them to image archive 128 or expanded memory image archive 105 for storage. Expanded memory image archive 105 provides storage, archiving, security, backup, and transmission services for digital images. WamiNet™ of Minneapolis, Minn. is an example of a suitable service provider for expanded memory image archive 105. Laser printer 130, which is capable of diagnostic-quality printing, furnishes hard copies of the digitally encoded images and records.

[0078] Administrative center 102 contains an account database 132 and a customer service system 134. Account database 132 contains personal information for each subscriber, which is linked to the patient's medical data stored in clinical database 118. Customer service system 134 provides assistance for all non-technical subscriber problems, e.g., billing questions.

[0079] Web-enabler 104 receives diagnostic-quality images from image server 126. In addition to storing the images on a short-term basis (up to 30 days), web-enabler 104"web-enables" the files for further transmission through Internet 99. Among other things, web enabling involves compressing a file and placing the file in a database at a particular address and location for later accessing of the file.

[0080] Expanded memory image archive 105 receives diagnostic-quality images requiring large amounts of memory storage. For example, mammography studies, requiring on the order of 168 MB each, preferably would be stored in expanded memory image archive 105.

[0081] The plurality of primary physicians 106, including primary doctors' offices and radiological imaging centers, provides consultations with patients to assist in formulating focused medical records. The plurality of primary physicians 106 also serves as a location for registering patients, by for example e-mail, telephone, or facsimile machine. Finally, the plurality of primary physicians 106 also accesses and updates patient medical records, as authorized by the patients.

[0082] The plurality of referral physicians 108 includes specialists and radiologists who receive through the Internet 99 medical records for further analysis, e.g., second opinions. The plurality of referral physicians 108 may also access and update patient medical records if authorized by the patient.

[0083] Finally, the plurality of patients 110 access their individual medical records through the Internet 99 from home or another personal Internet access workstation, or from an Internet access workstation at a primary physician location.

[0084] The preferred embodiment of the present invention is implemented as a website-accessible database on the Internet that gathers and disseminates information related to patient medical records. Users, e.g., patients and physicians, can access clinical database 118, account database 132, image archive 128, web-enabler 104, and expanded memory image archive 105 via the website. A user enters the appropriate website address (e.g., URL) to obtain access to these databases. Using a series of web pages (described below), users can enter, modify, and obtain information contained in the server databases.

[0085] According to a preferred embodiment, the hardware components of the system include three servers, a backup device, and remote access hardware (e.g., modem, encrypted TCP/IP access). The three servers, e-mail server 112, web server 114, and image server 126, are preferably Micron NetFrame 3100/500 Mhz processor servers with 512 MB RAM, and 20 GB storage (50 GB minimum for image server). Operating on the hardware, the preferred software includes Windows NT Server 4.0 (SP5), Internet Information Server 4, Cold Fusion 4.01, Microsoft Access 2000, and SQL Server.

[0086] Although FIG. 1 shows servers, archives, and databases as separate network components, one of ordinary skill in the art would appreciate that these components could be combined into fewer components or into a single component with distinct applications, to accomplish the individual functions of each component. For example, clinical database 118 and image archive 128 could be a single database segmented to handle the files stored by clinical database 118 and image archive 128. As another example, scanner 117 and digitizer 122 could be single machine providing the functions of both scanner 117 and digitizer 122.

[0087] System Operation

[0088] Implemented within the above-described system architecture, the present invention provides a method for establishing and managing patient medical records, including specialized mammography studies. This method involves a general business procedure supported and facilitated by interactions through a website. For clarity, the following discussion first describes generally the features of the present invention, and then traces the specific business procedures and website operation through the logical progression of establishing and managing a patient medical record.

[0089] Features

[0090] In providing a medical record management service, the present invention offers the following general features: 1) My Medical Folder; 2) Global-ER; 3) MammoTracker; and 4) MammoNet.

[0091] My Medical Folder is a software application designed to assist a patient in working with a primary physician to establish a focused medical record. The structure of My Medical Folder generally corresponds to a traditional medical chart and is designed to prompt the patient and physician for information necessary for future diagnoses and care. According to a preferred embodiment, physicians are offered monetary incentives (e.g., 2-3 paid consultations per year) to assist patients in entering and maintaining medical records in My Medical Folder.

[0092] Global-ER is a software application that presents the most critical information necessary in an emergency situation. Having readily available, clear information avoids unnecessary and costly medical procedures, and increases the probability of obtaining successful treatment. Although described herein as a part of My Medical Folder, Global-ER is also a stand-alone feature, providing key emergency information to, for example, customers of health care Internet portal companies, health care service payors (e.g., HMOs, Preferred Provider Organizations (PPOs), and large employers), pharmaceutical benefit management companies, and disease-management companies. Additionally, as a further embodiment of Global-ER, the critical information stored in Global-ER is downloaded onto a portable PERC to be carried at all times by the patient. In a related embodiment, the entire My Medical Folder or a portion thereof is downloaded onto a portable Super PERC to be carried by the patient.

[0093] MammoTracker is a software application that collects and tracks information (but not images) related to breast imaging and procedures, such as mammograms, breast ultrasound examinations, and biopsy procedures. MammoTracker retains a series of prior mammogram results to aid detection of early indicators of problems and accurately track progress toward malignancy. MammoTracker can operate as a stand-alone application or can be integrated with either My Medical Folder, MammoNet, or both.

[0094] Finally, MammoNet is a system that acquires, stores, archives, tracks, and retrieves mammographic studies (i.e., diagnostic-quality images). MammoNet stores mammograms as digitally encoded files in an expanded memory archive. Depending on the Internet communication and display capabilities of a particular implementation of the present invention, a patient can electronically transmit the diagnostic-quality images to physicians for review or can print them out and deliver them as hard copies. Also, depending on these technical capabilities, MammoNet can either be a stand-alone system or can be integrated with My Medical Folder or MammoTracker or both, such that a patient can not only view and update summaries of mammography studies, but can also retrieve and view the images associated with each study.

[0095] Business Procedures and Website Operation

[0096] In light of the general features of the present invention described above, this section tracks a patient's enrollment and use of the system and method of the present invention. The system and method include the following principal functions: 1) patient account registration; 2) medical data entry; 3) medical data retrieval and transmission; and 4) customer service and technical support. For each of these functions, the discussion below explains the actions taken by the patients and physicians, the interaction between the system components, and the concurrent operation of the website, most often depicted by screen shots that the user views at each step.

[0097] As an overview, FIG. *2a* illustrates the preferred site map of the present invention. When a user, e.g., a patient or physician authorized by the patient, first enters the website, the system displays a home page, as is represented by the root directory **200** of the site map in FIG. *2a*. As FIG. *2a* shows, the user can enter five different menu options: Sign Up **208** (account registration), My Medical Folder **210**, MammoNet **212**, Global-ER (which is in the same root directory as My Medical Folder), and MammoTracker (which is also in the same root directory as My Medical Folder).

[0098] FIG. *2b* shows a representative embodiment of the home page that is displayed upon entry into the website. The home page contains introductory information regarding the site, some explanatory remarks, and several option buttons. Preferably, the user navigates through the system using the options presented on the home page. Preferably, the home page displays to the user a number of options (e.g., in the form of buttons, or highlighted or underlined text, displayed on the home page, which are clicked-through to make a selection).

[0099] For example, as shown in FIG. *2b*, a Sign Up button **208** activates the patient registration GUI. Clicking on My Medical Folder button **210** activates the GUI that presents data fields into which medical data is entered, for storage in the clinical database **118**. The Global-ER **214** and MammoTracker **216** buttons display particular subsets of medical data taken from My Medical Folder **210**. Global-ER **214** presents data on the most critical information necessary in emergency situations, such as background information, chronic conditions, emergency precautions, and information on current medicines that the patient is taking. MammoTracker **216** presents only mammography data. Clicking on MammoNet **212** launches the application that manages diagnostic-quality mammography studies. Finally, the home page preferably features three additional buttons for information links **220** (e.g., hyperlinks to related news information), "about us" information **222** (e.g., giving contact information and company information about the medical record management service provider, examples of which are shown in FIGS. *2c-2f*), and "help" information **224** (e.g., simple technical instructions for navigating website, an example of which is shown in FIG. *2g*).

[0100] The home page acts as the gateway to the functions of the present invention. Clicking on the buttons brings up more screens with more options, presented as structured tabs. At any point during interaction with the website, the user can return to previous screens by clicking the options buttons. Alternatively, the applicant can use the "go to" or "back and forward" features of an Internet browser application. FIG. *2h* illustrates the structured tabs presented on the My Medical Folder, Global-ER, MammoTracker, and MammoNet screens.

[0101] 1) Patient Account Registration

[0102] Referring to FIG. *3a*, according to the preferred embodiment of the present, a patient first registers with the medical record management service, for example, through the Internet or by facsimile machine. Alternatively, although not shown on FIG. *3a*, the patient could also register by calling a telephone call center. In either case, the patient provides general background and contact information, such as name, address, telephone number, social security number, billing information, date of birth, name of primary care physician, and e-mail address. This information is stored in the account database **132**. Also at the time of registration, the patient pays any required registration fee.

[0103] For facsimile registration, a patient completes a form asking for the required registration information. The

form could be completed and transmitted from any location having a facsimile machine. However, most likely, the form is completed at the office **300** of a primary physician or radiologist. A designated representative **302** at the office proofreads the form **304**, provides any assistance the patient may need, faxes the form to administrative center **102**, and collects the registration fee. Administrative center **102** receives the form, keys the information into a new account in account database **132**, and assigns a unique patient identification (UPI) and password to the patient. Administrative center **102** then sends a return facsimile to the office **300** confirming the successful account registration and informing the patient of her account access information (UPI and password).

[0104] For online registration, the patient uses an Internet computer workstation **306** to access the website of the present invention. On the home page, as shown in **FIG. 2***b*, the patient clicks on Sign Up button **208** to launch the registration GUI. The registration GUI returns a welcome page (**FIG. 3***b*) followed by a terms and conditions page (FIGS. 3*c*). Upon acceptance of the terms and conditions, the registration GUI prompts the patient for a username, social security number (or if the patient so desires, a surrogate series of computer generated numbers and letters), and date of birth (**FIG. 3***d*); a password, password questions, and e-mail address (**FIG. 3***e*); product selections and a promotional code, if any (**FIG. 3***f*); and, payment information (**FIG. 3***g*). Having received all registration information, the registration GUI then asks the patient to review and confirm the entered information (**FIG. 3***h*) and returns a confirmation that the account is approved (**FIG. 3***i*). The registration GUI assesses the registration fee in accordance with the provided payment information, e.g., charges a credit card. In addition to confirming account approval as shown in FIG. 3*i*, the registration GUI provisioned in administrative center **102** sends a separate communication, e.g., e-mail, informing the patient of her UPI and password.

[0105] As an alternative to completing forms, entering data through the Internet, and calling a telephone call center, the present invention can obtain patient demographic data directly from existing databases, such as the Radiology Information System (RIS) or Hospital Information System (HIS), depending on the systems and interfaces in operation at a particular site.

[0106] The present invention provides the patient with ownership and control of her own medical record, controlling access to the medical records using UPIs, passwords, and physician access codes. Thus, before opening a medical record, a patient must log in and provide the UPI and password. A physician uses a separate access code (and the UPI), which allows access to a patient's record when the patient has granted permission for viewing and/or updating. In the preferred embodiment of the present invention, a UPI is an 18-digit number unique to every patient, which is used to associate all records of a patient. The first nine digits of the UPI are the patient's social security number, or if the patient desires not to use her social security number, are a series of nine random numbers and letters. The tenth digit indicates whether the preceding nine are the patient's social security number or are random, e.g., a "1" would indicate a social security number and a "0" would indicate random numbers and letters. The remaining eight digits are the patient's date of birth, e.g., a four digit year, a two digit month, and a two digit day. With this unique tag, the present invention easily matches and gathers a patient's records across different proprietary patient information systems, such as non-affiliated clinics and hospitals.

[0107] 2) Medical Data Entry

[0108] Referring to **FIG. 4**, the method by which medical records are entered into the patient medical record service depends on the format of the medical record. The three different formats include textual records **400**, scanned records **402**, and medical images **404**.

[0109] a) Textual Records

[0110] Textual records **400** are simply keyed into the website GUIs and stored in clinical database **118**. If a patient registers for the service at a physician's office, the patient and either a staff associate or a doctor work together to enter the pertinent data into My Medical Folder at that time. If the patient registers from home or another Internet workstation outside of the physician's office, the patient enters the data in the appropriate fields and reviews the entered clinical data with her primary physician during the next office visit and medical record consultation.

[0111] FIGS. 5*a*-5*ab* illustrate the various website GUIs a patient navigates through to enter medical data. **FIG. 5***a* is the welcome page for My Medical Folder. **FIG. 5***b* is the login page required to gain access to the medical record. Once access is accepted into My Medical Folder, the patient or physician can access and enter data into several different components of My Medical Folder, including Quick Look, Background Information, My Medicine Chest, Chronic Conditions, My Office Visit, Lab Data, Radiology, Mammography Tracking, Specialists, Procedures, Prevention/Screening, Emergency Contacts, and Private Information. While browsing the website of the present invention and entering data, the patient or physician can access these components at any time by clicking on the structured tabs displayed on every screen. Each screen resembles a form from a conventional medical chart and includes explanatory remarks and instructions.

[0112] Immediately after login, as shown in **FIG. 5***c*, the GUI presents the Quick Look record, a summary sheet that lists the patient's important medical information and serves as a valuable overview for the physician. In accordance with the description for each data field, the patient or physician enters the data. After completing the Quick Look record, the patient and/or physician clicks on each tab and enters the appropriate data in each field. The Background Information (**FIG. 5***d*), My Medicine Chest (**FIGS. 5***e* and *5f*), and Chronic Conditions (**FIGS. 5***g* and *5h*) records are summaries of a patient's medical history and current and historic medication information. The My Office Visit record (**FIG. 5***i* and *5j*) is a list of office visit encounter forms and diagnostic illness assistance. The Lab Data (**FIGS. 5***k*-*5n*) and Procedures (**FIG. 5***v*) records are summaries of tracking for results of laboratory tests and diagnostic procedures. The Radiology record (**FIGS. 5***o* and *5p*) is a summary of radiological assessments, notes, and reports, with links to the actual images (discussed below). The Mammography Tracking record (**FIGS. 5***q* and *5r*) is listing of a patient's mammography history, which is linked to MammoTracker and can be linked to MammoNet if the patient purchases the product. The Specialists record (**FIGS. 5***r*-*5u*) is a list of specialists

and other consulting physicians, including scanned specialist reports when appropriate. The Prevention/Screening record (FIGS. 5w-5z) is a summary of tracking and scheduling of preventative health topics, such as cancer screening. The Emergency Contacts record (FIG. 5aa) contains information a patient wishes to make available to a health care facility or to ambulance or emergency personnel in case of an emergency. The Private Information record (FIG. 5ab) includes information that only the patient can access, and does not allow access by physicians who are authorized to view the remaining records. In addition, the Private Information record includes software applications that track health care related concerns such as flexible spending accounts, copayment summaries, and tax summaries. FIG. 5ah illustrates a page of a software application that tracks a patient's flexible spending account.

[0113] For the My Office Visit record (FIG. 5i and 5j), a patient would not complete the record immediately after service registration, but would instead enter data in the record prior to an office visit. The My Office Visit record prompts the patient for information that will generally be requested by the patient's physician at the time of the visit, e.g., information concerning an illness for which the patient is visiting the physician. The My Office Visit record also prompts the patient to perform certain actions, such as taking her temperature or carefully describing symptoms. In addition, the My Office Visit record includes forms designed to facilitate scheduled and periodic office visits for chronic illnesses, such as diabetes or cardiovascular diseases. The forms educate the patient in advance about the condition, enable the patient to have more informed interactions with the physician, and allow the patient to be more involved in understanding and complying with the physician's choice of treatment protocols.

[0114] In addition to manually entering textual records 400, a further preferred embodiment of the present invention acquires textual data directly from existing databases, e.g., HIS and RIS. In this manner, web server 114 interfaces directly with a database and downloads the information corresponding to the data fields of My Medical Folder.

[0115] For MammoTracker, a patient or physician enters data in a manner similar to My Medical Folder, but only for details concerning breast cancer screening. After clicking on the MammoTracker button 216 as shown in FIG. 2b, the patient or physician logs in and enters data in the various data fields, as shown in FIGS. 5ac through 5ag.

[0116] b) Scanned Documents

[0117] In contrast to textual records 400, scanned documents 402 require a somewhat more involved method of data entry, as shown in FIG. 4. Scanned records 402 include such documents as EKGs, laboratory test results (reports), and echocardiograms, which generally cannot be easily summarized in textual form and for which a picture is most appropriate. Thus, to have a more useful medical record, these types of documents must be scanned and stored as image files in clinical database 118 under the appropriate tabbed records in My Medical Folder. The image files do not have to be of diagnostic-quality, rather only of legible quality suitable for clinical purposes.

[0118] If the original record is on paper, either the original or a copy is forwarded to operations center 100, where it is logged in, matched to the patient's account, and scanned into clinical database 118 using scanner 117 and image server 126. The type of electronic file into which the record is scanned depends upon the standard required by clinical database 118, e.g., JPEG or PDF files. Alternately, the original paper record is faxed and received by image server 126 for storage in clinical database 118 as an electronic facsimile file. As another option, if the original record is already an electronic file, the record can be e-mailed directly to web server 114 of operations center 100, and stored in clinical database 118 by image server 126.

[0119] c) Medical Images

[0120] Because of the need for diagnostic quality, medical images 404 require the most complex method for data entry. Medical images 404 are any visual medium that must be of diagnostic-quality to be clinically useful, e.g., MRIs, CTs, and mammograms. The methods for entering medical images fall under two principal categories: non-mammography images and mammography images. Preferably, a patient uses My Medical Folder to manage non-mammography images and uses MammoNet to manage mammography images. The separate methods for storing mammography studies are necessary to accommodate specialized needs, such as large image files and computer-aided detection.

[0121] FIG. 6 illustrates the method for storing non-mammography medical images into a patient medical record. First, a patient retrieves (borrows) the medical images 600 from the imaging center or physician's office 602 that owns the records. The patient then delivers the medical images 600 to operations center 100, where the studies are logged in. A technician at operations center 100 scans medical images 600, which are then displayed on image workstation 604, preferably in a DICOM (Digital Imaging and Communications in Medicine) format. The technician then tags the digitized medical images with the patient's name and UPI. With the patient preregistered, image workstation 604 queries account database 132 using the patient's name and UPI to retrieve the information necessary for completing bills.

[0122] The technician forwards the digitized images from image workstation 604 to image server 126. Image server 126 sends the digitized images through web server 114 to web-enabler 104 to be web-enabled and, optionally, to be stored in a short-term cache of the web-enabler 104, e.g., a 0-30 day cache. Web-enabler 104 is a web file management service, such as Amicas™ of Massachusetts. Image server 126 is provisioned with cooperative software, e.g., Amicas software, to communicate with web-enabler 104. Web-enabler 104 web-enables the files by, among other things, compressing the files and indexing them for subsequent accessing. After web-enabling the files, web-enabler 104 sends them back to image server 126 through web server 114 for storage in an intermediate cache of image archive 128. With files in web-enabled form, an authorized user, such as a patient or physician, can access the digitized images through My Medical Folder.

[0123] In a preferred embodiment, as a backup of the web-enabled intermediate cache, before the digitized image files are forwarded to web-enabler 104, a copy of the raw, uncompressed data is stored in the long-term cache of image archive 128. Therefore, if the web-enabled files in the

intermediate cache of image archive **128** are somehow lost or unavailable, the raw data can be retrieved from the long term cache, resent to web-enabler **104**, returned, and made available again to the patient or physician. As additional protection, image server **126** can also store the digitized image files in its short-term cache.

[0124] FIGS. *7a-7e* illustrate preferred methods for acquiring mammography images. For these medical images, a critical aspect for streamlining data entry is the immediate acquisition and digital conversion of mammography images. This aspect eliminates the possibility of misplacing or losing the original mammogram films. Another unique aspect of these medical images is the large amount of memory storage they require, on the order of 168 MB for each mammography study. In addition, the method for storing mammography records must also incorporate the valuable assistance provided by computer-aided detection. Although FIGS. *7a-7e* and the corresponding narrative describe a method for acquiring mammography images, one of ordinary skill in the art would recognize that the method applies equally well to other types of medical images, especially those requiring diagnostic-quality displays, large amounts of memory storage, and computer-aided detection.

[0125] The three principal methods by which mammograms are stored in a patient medical record depend on whether the imaging center taking the mammograms has a digitizer and a CAD system, e.g., ImageChecker™ by R2 Technology. Typically, imaging centers have no digitizer and no CAD system, have a digitizer but no CAD system, or have a CAD system and a digitizer. FIGS. *7a*, *7b*, and *7c* illustrate these scenarios, respectively. In addition, FIGS. *7d* and *7e* are a flowchart outlining the general workflow of the acquiring mammograms and storing them in patient medical records, encompassing the three scenarios described below. Unless noted otherwise, each step illustrated in FIGS. *7d* and *7e* corresponds to the three types of imaging centers.

[0126] As shown in FIG. *7a*, when an imaging center does not have a CAD system or a digitizer, the patient borrows the hard copy mammograms **700** and delivers them to operations center **100**. A technician at operations center **100** logs the receipt of the hard copy mammograms **700** and, using digitizer **122**, digitizes them, preferably into DICOM files, such that they appear on image workstation **604**. The technician then tags the digitized medical images with the patient's name and UPI. With the patient preregistered, image workstation **604** queries account database **132** using the patient's name and UPI to retrieve the information necessary for completing bills. Image workstation **604** then forwards the digitized images to image server **126**, which sends them for long term storage to expanded memory image archive **105** through a network accessing device (NAD) **702**.

[0127] Concurrent with digitizing and storing images, a CAD system **124** digitizes and analyzes the hard copy mammograms **700**. Optionally, digitizer **122** and the digitizer integral to CAD system **124** are the same digitizer. CAD system **124** electronically marks the images to note possible indications of disease and presents both the hard copy mammograms **700** and the marked electronic images to the radiologist operating CAD system **124**. If CAD system **124** and the CAD system radiologist find no problems, operations center **100** returns the hard copy mammograms **700** to imaging center **106**. If CAD system **124** and the CAD system radiologist do uncover a suspicious area and/or if the CAD system reading differs substantially from the underlying reading, the CAD system radiologist generates a report to send back to imaging center **106** with the hard copy mammograms **700**. Optionally, if imaging center **106** does not participate in the service of the present invention, operations center **100** sends the hard copy mammograms **700** and a report (if needed) directly to the patient.

[0128] FIG. *7b* shows the acquisition, analysis, and storage of mammograms for an imaging center **106** that has a digitizer **122** but no CAD system. In this scenario, a technician at imaging center **106** performs the mammography study and produces the hard copy mammograms **700**. The technician then immediately digitizes the hard copy mammograms **700** with digitizer **122**, preferably in a DICOM format. The digitized images appear on image workstation **604**. The technician then tags the digitized medical images with the patient's name and UPI. With the patient preregistered, image workstation **604** queries account database **132** using the patient's name and UPI to retrieve the information necessary for completing bills. Image workstation **604** then forwards the digitized images through an image center NAD **710** and an operations center NAD **702** to image server **126**. Image server **126** then sends the images for long term storage to expanded memory image archive **105** through NAD **702**.

[0129] As operations center **100** is receiving and forwarding the digitized images to expanded memory image archive **105**, operations center **100** runs the digitized images through CAD system **124** as described for FIG. *7a*, but using digitized files instead of hard copy images. If the radiologist operating the CAD system **124** detects a problematic area and/or if the CAD system reading differs substantially from the underlying reading, the radiologist sends a report back to imaging center **106** by such means as e-mail or conventional mail.

[0130] FIG. *7c* shows the acquisition, analysis, and storage of mammograms for an imaging center **106** that is fully equipped with a CAD system **124** and a digitizer **122**. In this scenario, imaging center **106** performs the digitizing and CAD checking of the images and simply forwards the digitized image to operations center **100** for storage in expanded memory image archive **105**. If the radiologist operating CAD system **124** detects a problem, the radiologist of imaging center **106** generates an internal report.

[0131] As shown in FIG. *7c*, a technician at imaging center **106** performs the mammography study and produces hard copy mammograms **700**. The technician immediately digitizes the hard copy mammograms **700** with digitizer **122**, preferably in a DICOM format. Image workstation **604** displays the digitized image while, simultaneously, CAD system **124** marks problematic areas in the images for further evaluation by an interpreting radiologist, who generates a report if necessary. The technician then tags the digitized medical images with the patient's name and UPI. With the patient preregistered, image workstation **604** queries account database **132** using the patient's name and UPI to retrieve the information necessary for completing bills. Image workstation **604** then forwards the digitized images and report, if generated, through an image center NAD **710** and an operations center NAD **702** to image server **126**.

image server **126** then sends the images and report, if generated, for long term storage to expanded memory image archive **105** through NAD **702**. Preferably, before forwarding the images, image server **126** performs quality assurance checks on the images to verify diagnostic quality.

[0132] In the above three scenarios, each participating institution provides a telecommunications link to the MammoNet network. Additionally, in the preferred embodiment, to receive the hardware and software at no charge, each participating provider provides the staffing necessary to complete registration and digitizing, and in addition, guarantees a minimum number of patients annually, e.g., approximately 2500/year or 10/day.

[0133] As an alternative to the above three scenarios, the present invention anticipates advances in electronic display technologies that will allow physicians to read medical images without ever having to print hard copies. This advance will obviate the need for a digitizer. Thus, an alternate representative embodiment of the present invention provides that an imaging center records digitized images directly from a medical imaging machine, e.g., an x-ray machine. The digitized images would be electronically displayed for the physician's read and would also be analyzed by a CAD system. The imaging center would then send the digitized images and an interpreting radiologist's report, if generated, to the operations center for storage in a patient's medical record.

[0134] Once a patient enters her mammogram studies into the MammoNet system, the system and method of the present invention offer the patient the opportunity to integrate the MammoNet digitized mammograms into her complete medical record vault of My Medical Folder or as a part of MammoTracker. If Internet communications and hardware capabilities (especially display hardware) permit the transfer of the large image files associated with mammography studies, the present invention provides links within MammoTracker by which images can be retrieved from MammoNet. If technical capabilities do not handle the large image files, the MammoNet digitized mammograms are integrated into the complete medical record by listing summaries of the results in MammoTracker and providing instructions on how to physically retrieve the images through MammoNet.

[0135] In addition to patients of participating sites, the present invention can enroll patients of non-participating sites and store the mammograms of those non-participating sites. In such case, the patients mail their existing studies to operations center **100** for digitization and storage.

[0136] 3) Medical Data Retrieval and Transmission

[0137] As provided by the present invention, data retrieval, like data acquisition, is convenient, accurate, easily available, and secure. Each patient has both a unique identifier and a password. State-of-the-art encryption technology secures the website. **FIGS. 8***a* and *8b* illustrate the methods by which the present invention retrieves medical records. **FIG. 8***a* shows retrieval of records and non-mammography images. **FIG. 8***b* shows retrieval of mammography images, from MammoNet. Although shown in the context of mammography images, one of ordinary skill in the art would appreciate that the system and method of **FIG. 8***b* applies to other medical images as well, especially those requiring diagnostic-quality display, large amounts of memory storage, and computer-aided detection.

[0138] Since My Medical Folder and MammoTracker store information in specific, identifiable fields, authorized users, such as patients and physicians, can search by field to obtain particular information required for a particular situation. For example, should a patient have an appointment with a new physician, the patient can search for and retrieve only pertinent demographic and insurance information and can send that information electronically or by fax to the new physician. Having accessed and transmitted the specific information in advance, the patient avoids the time-consuming exercise of completing paperwork at the time of the visit. As an alternate to searching, patients and physicians may browse the patient medical record using the structured tabs.

[0139] As **FIG. 8***a* shows, an authorized user, such as a patient or physician, accesses the medical record by first opening the web page of the present invention and logging in with the UPI and password or access code. Then, using a search function of the website (not shown in the figures), authorized user **111** formulates a query for the desired records (among My Medical Folder and MammoTracker) and sends the query to web server **114** of operations center **100**. Responding to the query, web server **114** consults clinical database **118** for textual and scanned records, and consults image server **126** and image archive **128** for diagnostic-quality images. After identifying and retrieving the appropriate records, web server **114** returns the records through the Internet for display on the workstation of authorized user **111**. Optionally, if the Internet communications or workstation hardware does not support diagnostic-quality images, a notification is sent to authorized user **111** reporting that the records have been pulled and/or copied, and will be returned via conventional means, e.g., by mail.

[0140] As shown in **FIG. 8***b*, authorized user **111** (e.g., a patient, physician, or radiologist) accesses mammography images in MammoNet by facsimile or e-mail communication received by web server **114**, by telephone request received by technicians at operations center **100**, or by an online request through the Internet and web server **114**. For facsimile, e-mail, and telephone requests, technicians at operations center **100** key the queries into image server **126**. For online requests, image server **126** automatically receives the queries.

[0141] In response to the retrieval request, image server **126** uses the patient's UPI to look for the requested images in its short term cache and, if none are found, sends a search request to expanded memory image archive **105**. Expanded memory image archive **105** retrieves the digitally encoded files and returns them to image server **126**. If the Internet communications and the workstation of authorized user **111** can handle the large image files, image server **126** returns the images through web server **114** to the workstation of authorized user **111**. If, for example, the technical capabilities are lacking, or if, for example, the physician prefers to examine a hard copy, image server **126** prints the digital files using laser printer **130**, and forwards the resulting diagnostic-quality images (to authorized user **111** (e.g., the patient or physician) by conventional means, e.g., mail.

[0142] A further preferred embodiment of the present invention provides immediate means for accessing and retrieving medical records. A first variation of this embodiment is a means for conveying critical medical information in emergency situations. A second variation is an immediate means for conveying a patient's entire medical record.

[0143] Once the patient has entered data into the My Medical Folder and MammoTracker, the present invention marks the information most critical for an emergency situation. The present invention then duplicates this information

under the Global-ER tab as a single, concise GUI that displays this critical emergency data. In this manner, an emergency physician with Internet access can bring up the patient's medical record and immediately access the Global-ER file from the home page. The emergency physician would gain access to the Global-ER by asking the patient for the UPI and password, by looking at an information card the patient is carrying, or, if the patient agrees in advance to allow unrestricted access to the Global-ER page, by simply clicking on Global-ER and skipping the login (UPI and password).

[0144] Further, to make emergency data retrieval even more immediate, the present invention, in the first variation of this embodiment, provides a Patient Power Emergency Room Carrier (PERC) that stores the information listed in Global-ER in a portable form. The patient carries the PERC at all times, e.g., the PERC would be stored in a small memory card attached to a key chain. An example of a suitable storage card is a flash data storage product, like those produced by SanDisk™ Corporation of Sunnyvale, Calif. (e.g., PC Card ATA FlashDisk or CompactFlash).

[0145] An alternate embodiment utilizes a more durable and secure version of a flash memory card, classified as a Personal Information Carrier (PIC), also produced by SanDisk™ and modified by Informatech, Inc.™ (ITI). This PIC (also known as a P-Tag) is interchangeable with CompactFlash, and is used, for example, as a modified dog tag for U.S. Army soldiers. In any of these forms, the memory card is compatible with hospital computer terminals, e.g., using PCMCIA interfaces or CF ports provisioned at each hospital, provided by the medical record management service provider if necessary.

[0146] In addition, technology is emerging that will allow a P-Tag or other portable memory storage device to interface directly with the USB port of a desktop computer. Examples of this technology include the Thumbdrive™ by Trek 2000 International Ltd. of Singapore and the Q.™ USB hard drive by Agaté Technologies, Inc. of Milpitas, Calif. When appropriate and necessary, the present invention includes providing these interfaces, adapters, and emerging technologies. Thus, instead of requiring the emergency room staff to log onto the Internet and access the critical information page, the PERC enables instant plug-in and display capability.

[0147] According to the second variation of this embodiment, a Super PERC includes a patient's entire medical record behind the critical information, which would appear first. Thus, in addition to emergency applications, the patient could use the Super PERC to carry medical records around for viewing by individual physicians. Such applications are especially beneficial for patients who travel frequently and are often away from their primary physicians, e.g., airline pilots and flight attendants.

[0148] The amount of records that can be stored on the Super PERC is limited only by the storage capacity of the card. Provided with enough storage, a patient could use Super PERC instead of the website to store medical records. This option is beneficial in attracting patients to the service who may be uncomfortable posting private information on the World Wide Web, even though the information may be securely stored.

[0149] Whether the Super PERC is used exclusively or is used as a supplement to the website storage, operations center **100** would routinely update the Super PERC with changes made to the website records (e.g., Global ER and My Medical Folder). Optionally, a patient could update the Super PERC provided that the patient has access to the required computer programming and hardware. The PERC would also be updated in this manner.

[0150] In addition to updates that download new information from operations center **100** to a PERC or Super PERC, an alternate embodiment synchronizes operations center **100** and PERC or Super PERC in a two-way flow of data. In this manner, records could be changed on a PERC or Super PERC and uploaded to operations center **100**. As one skilled in the art would appreciate, this implementation would require a stand-alone program operating on a patient's personal computer or handheld device. The program would read and make changes to a local copy of the patient's data. This implementation would also require a method for synchronizing the local and web-based copies of the patient's data. Because changes can be made to both copies concurrently, the synchronization method would identify the most recent records on each copy and would resolve conflicts between the copies, such as when a single record is modified on both copies in between synchronizations.

[0151] Related to the privacy concerns addressed by Super PERC, an alternate embodiment of the present invention provides the software applications of the present invention on a compact disk or other portable storage medium, instead of through the Internet. In this manner, a patient leery of posting information on the web can simply load the applications on her personal computer and save the medical record information to her computer's hard drive. The patient would then bring the medical record to the service provider on a portable storage medium, e.g., a floppy disk, so that the service provider could download the information onto a PERC or Super PERC. Alternately, the patient could obtain the hardware necessary to perform the downloading. Physicians would also have copies of the software applications so that the patient could bring her medical record to the physician's office and update it with the physician without using the web-based applications and data storage. As necessary, the service provider would provide updates to the patients and physicians for the non-web based software applications.

[0152] 4) Customer Service and Technical Support

[0153] As shown in **FIG. 9**, according to a representative embodiment, customer service and technical support is a feature of the present invention. Operations center **100** provides technical support by having technical representatives **900** available by telephone and e-mail to solve problems such as data entry and data retrieval, as related to them by authorized user **111** or customer service representatives **902**. From operations center **100**, the technical representatives **900** can access e-mail server **112** for technical data and can perform diagnostic checks on the remaining components of operations center **100**, e.g., web server **114**, image server **126**, clinical database **118**, web-enabler **104**, and expanded memory image archive **105**.

[0154] For customer service, administrative center **102** has customer service representatives **902** available by telephone and e-mail to answer billing questions or other administrative concerns, as raised by authorized user **111** or technical service representatives **900**. Customer service representatives **902** have access to account database **132** and customer service system **134** to meet these needs. Customer service system **134** is a GUI that gives the customer service representatives **902** the information, e.g., billing and legal policies, necessary to respond to patient inquiries.

[0155] The foregoing disclosure of embodiments of the present invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many variations and modifications of the embodiments described herein will be obvious to one of ordinary skill in the art in light of the above disclosure. The scope of the invention is to be defined only by the claims, and by their equivalents.

What is claimed is:

1. A method for managing medical records comprising the steps of:

(a) establishing an account for a patient;

(b) electronically storing text information associated with the patient;

(c) electronically storing paper documents associated with the patient in files capable of producing legible images;

(d) electronically storing medical images associated with the patient in files capable of producing diagnostic-quality images;

(e) associating the text information, the files of the paper documents, and the files of the medical images with the account; and

(f) providing an authorized user with access to the text information, the files of the paper documents, and the files of the medical images through a system.

2. The method of claim 1, further comprising the step of paying a physician to assist the patient in electronically storing the text information, the paper documents, and the medical images.

3. The method of claim 1, wherein the step of electronically storing the text information comprises entering textual data through a graphical user interface in communication with the system.

4. The method of claim 1, wherein the step of electronically storing the text information comprises transmitting textual data from an existing database.

5. The method of claim 4, wherein the existing database is one of Radiology Information System and Hospital Information System.

6. The method of claim 1, wherein the step of electronically storing the paper documents comprises one of scanning, faxing, and e-mailing the paper documents.

7. The method of claim 1, wherein the step of electronically storing the medical images comprises scanning the medical images into a high-resolution format file.

8. The method of claim 1, wherein the step of providing an authorized user with access comprises the steps of:

prompting the authorized user, through a graphical user interface, to query the system for a desired medical record, wherein the desired medical record is one of text information, a paper document, and a medical image;

retrieving the desired medical record from the system; and

transmitting the desired medical record through the graphical user interface to the authorized user.

9. The method of claim 8, wherein if the desired medical record is too large for efficient transmission, or if the authorized user does not have hardware capable of displaying the desired medical image, then the method comprises printing a hard copy of the desired medical record and forwarding the hard copy to the authorized user.

10. The method of claim 1, further comprising marking portions of the text information, the files of the paper documents, and the files of the medical images as critical information that is needed in an emergency situation, and

wherein the step of providing an authorized user with access comprises displaying the critical information on a single graphical user interface.

11. The method of claim 10, further comprising storing the critical information in a portable form.

12. The method of claim 11, wherein the portable form is one of a memory card and a personal information carrier.

13. The method of claim 1, wherein the text information, the paper documents, and the medical images are electronically stored in a portable form.

14. The method of claim 1, wherein the authorized user is one of a physician, a relative of the patient, and the patient.

15. The method of claim 1, wherein the step of establishing the account for the patient comprises assigning a unique patient identification and password to the patient,

wherein the authorized user is the patient, and

wherein the step of providing the authorized user with access includes requiring that the authorized user provide the unique patient identification and password.

16. The method of claim 15, further comprising the step of assigning an access code to a physician,

wherein the authorized user is the physician, and

wherein the step of providing the authorized user with access includes requiring that the authorized user provide the access code of the physician and the unique patient identification of the patient.

17. The method of claim 15, wherein the unique patient identification comprises:

(i) a series of first digits corresponding to one of a social security number of the patient and a random series;

(ii) one or more second digits indicating whether the series of first digits is the social security number of the patient or is the random series; and

(iii) a series of third digits corresponding to a date of birth of the patient.

18. The method of claim 1, wherein the step of electronically storing the medical images associated with the patient in files capable of producing diagnostic-quality images comprises the steps of:

(i) retrieving the medical images;

(ii) scanning the medical images into digitized images;

(iii) tagging the medical images with a name of the patient and a unique patient identification of the patient;

(iv) web-enabling the digitized images; and

(v) storing the web-enabled digitized images for access by the authorized user.

19. The method of claim 18, wherein the step of scanning the medical images into the digitized images comprises displaying the digitized images on an image workstation and storing the digitized images in a DICOM format.

20. The method of claim 18, further comprising querying an account database using the name and the unique patient identification of the patient to retrieve information necessary for completing bills.

21. The method of claim 18, wherein before web-enabling the digitized images, the method further comprises the step of storing the digitized images in a cache.

22. A system for managing medical records comprising:

(a) a scanner that digitally encodes images of paper documents into files that are capable of producing legible images;

(b) a clinical database that stores the files that are capable of producing legible images and that stores text information;

(c) a digitizer that digitally encodes medical images into files that are capable of producing diagnostic-quality images;

(d) an image archive that stores the files that are capable of producing diagnostic-quality images;

(e) an image server in communication with the scanner, the clinical database, the digitizer, and the image archive,

wherein the image server receives the files that are capable of producing diagnostic-quality images from the digitizer and transmits the files that are capable of producing diagnostic-quality images to the image archive, and

wherein the image server receives the files that are capable of producing legible images from the scanner and transmits the files that are capable of producing legible images to the clinical database; and

(f) a web server in communication with the image server, wherein the web server provides a plurality of users with access to the files that are capable of producing legible images, to the text information, and to the files that are capable of producing diagnostic-quality images.

23. The system of claim 22, further comprising a web-enabler that receives the files that are capable of producing diagnostic-quality images from the image server, temporarily stores the files that are capable of producing diagnostic-quality images, and web-enables the files that are capable of producing diagnostic-quality images.

24. The system of claim 22, further comprising an expanded memory image archive in communication with the image server, wherein the expanded memory image archive provides additional memory for storing the files that are capable of producing diagnostic-quality images.

25. The system of claim 22, further comprising:

(i) an application that marks critical information in the clinical database and the image archive; and

(ii) a means for storing the critical information in a portable form.

26. The system of claim 25, wherein the means for storing the critical information in a portable form is one of a smart card, a flash card, a compact flash card, a personal information carrier, and a portable memory storage device that interfaces directly with a USB port.

27. The system of claim 22, further comprising a means for storing, in a portable form, the files that are capable of producing legible images, the text information, and the files that are capable of producing diagnostic-quality images.

28. The system of claim 22, further comprising an e-mail server in communication with the web server and the plurality of users, wherein the e-mail server facilitates web-based transmission of the files that are capable of producing legible images, the text information, and the files that are capable of producing diagnostic-quality images from the web server to the plurality of users.

29. The system of claim 22, further comprising an account database that stores contact information, demographic information, and financial information of a patient in an account,

wherein the files that are capable of producing legible images and the text information of the clinical database are associated with the account, and

wherein the files that are capable of producing diagnostic-quality images of the image archive are associated with the account.

30. The system of claim 22, wherein the plurality of users comprise patients, physicians, and relatives of patients.

31. A method for managing medical records comprising the steps of:

(a) providing a patient with a system that electronically stores medical records;

(b) paying a physician to identify medical records to be stored in an account of the patient in the system; and

(c) entering the identified medical records into the account of the patient.

32. The method of claim 31, further comprising the step of paying the physician to identify additional medical records to be stored in the account of the patient and to identify medical records to be removed from the account of the patient.

33. The method of claim 31, further comprising the step of giving the physician access to the account of the patient to update the medical records.

34. The method of claim 31, further comprising the step of providing the patient with ownership of the medical records in the account.

35. The method of claim 31, wherein the medical records include text information, paper documents, and medical images.

36. A method for managing medical image records of a patient comprising the steps of:

(a) registering with an operations center through an imaging center; and

(b) if the imaging center does not have a digitizer or computer-aided detection (CAD) system,

delivering hard copy medical images of the patient to the operations center,

digitizing the hard copy medical images into digitized images at the operations center,

analyzing the digitized images using a CAD system at the operations center,

generating a report at the operations center if a problem is detected in the digitized images,

storing the digitized images and the report, if generated, in an archive, and

returning the hard copy medical images and the report, if generated, to one of the imaging center and the patient.

37. The method of claim 36, further comprising the step of:

(c) if the imaging center has a digitizer but does not have a CAD system,

digitizing hard copy medical images of the patient into digitized images at the imaging center,

transmitting the digitized images to the operations center,

analyzing the digitized images using a CAD system at the operations center,

generating a report at the operations center if a problem is detected in the digitized images,

storing the digitized images and the report, if generated, in an archive, and

returning the report, if generated, to one of the imaging center and the patient.

38. The method of claim 37, further comprising the step of:

(d) if the imaging center has a digitizer and a CAD system,

digitizing hard copy medical images of the patient into digitized images at the imaging center,

analyzing the digitized images with the CAD system at the imaging center,

generating a report at the imaging center if a problem is detected in the digitized images,

transmitting the digitized images and the report, if generated, to the operations center, and

storing the digitized images and the report, if generated, in an archive.

39. The method of claim 38, wherein if the imaging center has a digitizer and a CAD system, the method further comprises ensuring diagnostic quality of the digitized images at the operations center before storing the digitized images in the archive.

40. The method of claim 38, further comprising the steps of:

(e) receiving a query for the digitized images at the operations center from an authorized user;

(f) retrieving the digitized images from the archive;

(g) transmitting the digitized images through a network to the authorized user, if the authorized user's network connection and workstation support diagnostic-quality images; and

(h) printing a copy of the digitized images and forwarding the copy to the authorized user, if the authorized user's network connection and workstation do not support diagnostic-quality images.

41. The method of claim 40, wherein the medical images are mammograms.

42. The method of claim 40, wherein the authorized user is one of the patient, a physician, and a relative of the patient.

43. The method of claim 40, wherein the query is one of a telephone call, a facsimile, an e-mail, and an online request.

44. The method of claim 40, wherein the step of registering comprises assigning a unique patient identification to the patient,

wherein the digitized images are associated with the unique patient identification, and

wherein the query references the unique patient identification.

45. The method of claim 44, wherein the query includes a password if the authorized user is the patient, and

wherein the query includes an access code if the authorized user is a physician.

46. The method of claim 38, wherein the problem is one of an indication of disease and a difference between the report and an underlying read of the hard copy medical images.

47. The method of claim 38, wherein the method further comprises:

(e) if the imaging center records digitized images directly from a medical imaging machine,

analyzing the digitized images using a CAD system at the imaging center,

generating a report at the imaging center if a problem is detected in the digitized images,

transmitting the digitized images and the report, if generated, to the operations center, and

storing the digitized images and the report, if generated, in an archive.

48. A system for managing medical records comprising the steps of:

(a) means for establishing an account for a patient;

(b) means for electronically storing text information associated with the patient;

(c) means for electronically storing paper documents associated with the patient in files capable of producing legible images;

(d) means for electronically storing medical images associated with the patient in files capable of producing diagnostic-quality images;

(e) means for associating the text information, the files of the paper documents, and the files of the medical images with the account; and

(f) means for providing an authorized user with access to the text information, the files of the paper documents, and the files of the medical images.

49. The system of claim 48, wherein the text information includes at least one of medical data, contact information, demographic information, and financial information associated with the patient.

50. The system of claim 48, wherein the paper documents include at least one of electrocardiograms, echocardiograms, and laboratory reports associated with the patient.

51. The system of claim 48, wherein the medical images are mammograms of the patient.

52. The system of claim 48, wherein the means for electronically storing text information, the means for electronically storing paper documents, and the means for electronically storing medical images comprise a portable memory storage device.

53. The system of claim 52, wherein the portable memory storage device is one of a smart card, a flash card, a compact flash card, a personal information carrier, and a portable memory storage device that interfaces directly with a USB port.

* * * * *

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(19) United States

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(54) PATIENT DIRECTED SYSTEM AND METHOD FOR MANAGING MEDICAL INFORMATION

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Publication Classification

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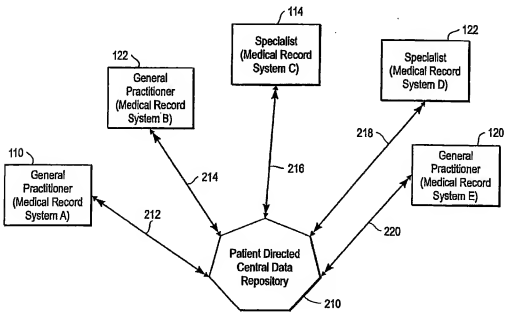
(52) U.S. Cl. 707/10; 707/3

(57) ABSTRACT

A system and method is provided for the management of a patient's medical records by a central data repository under the direction of the patient and enabled by an entity managing records on behalf of the patient. Medical records from a plurality of the patient's healthcare providers, including past and present healthcare providers, are maintained in this central repository in a way that provides a centralized, comprehensive, and accessible medical history of the patient, as well as a comprehensive organizational structure across all records. An embodiment has the patient directed central repository as the hub in a hub-and-spoke arrangement, where each spoke goes to one of the patient's healthcare providers, both past and present. The patient's medical records are collected from all the patient's healthcare providers, then classified, stored, and organized for use by the patient, healthcare providers, and any other authorized individuals. The records in the repository can be sorted and/or selected in several different ways and displayed to the patient or to his designated medical care providers, and to certain patient designated third parties.



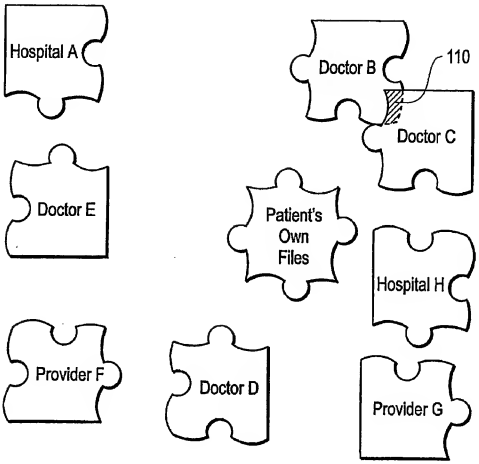


FIG. 1 (PRIOR ART)

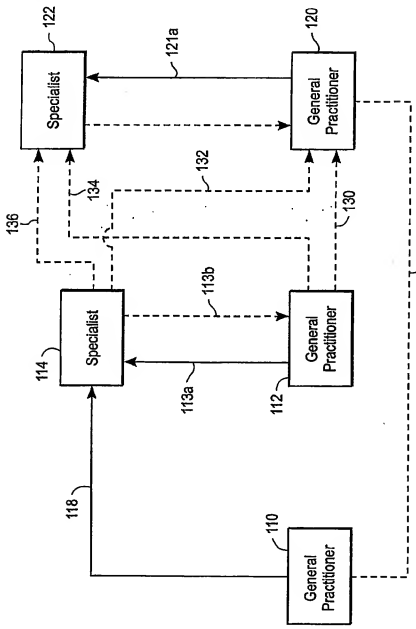


FIG. 2 (PRIOR ART)

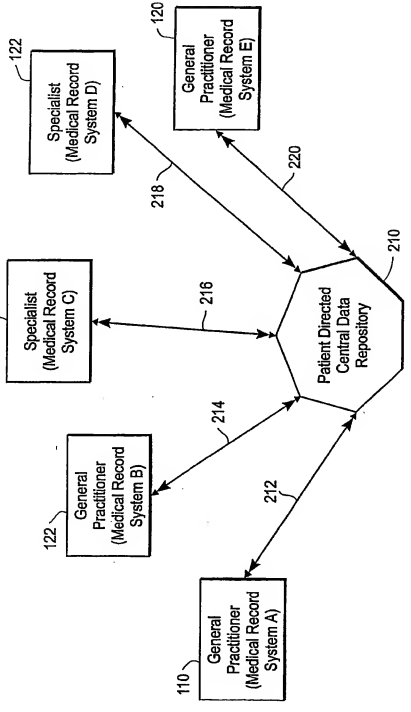

Patient Directed Central Data Repository
210
General Practitioner (Medical Record System A)
110
General Practitioner (Medical Record System B)
122
Specialist (Medical Record System C)
114
Specialist (Medical Record System D)
122
General Practitioner (Medical Record System E)
120
212
214
216
218
220

FIG. 3

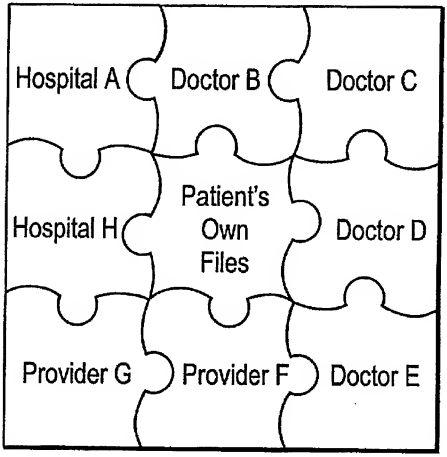

Hospital A
Doctor B
Doctor C
Hospital H
Patient's Own Files
Doctor D
Provider G
Provider F
Doctor E

FIG. 4

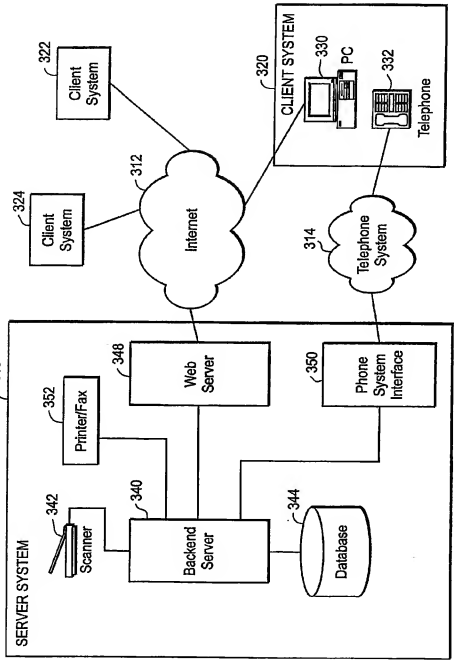

310
SERVER SYSTEM
342
Scanner
352
Printer/Fax
340
Backend Server
344
Database
348
Web Server
350
Phone System Interface
322
Client System
324
Client System
312
Internet
314
Telephone System
320
CLIENT SYSTEM
330
PC
332
Telephone

FIG. 5

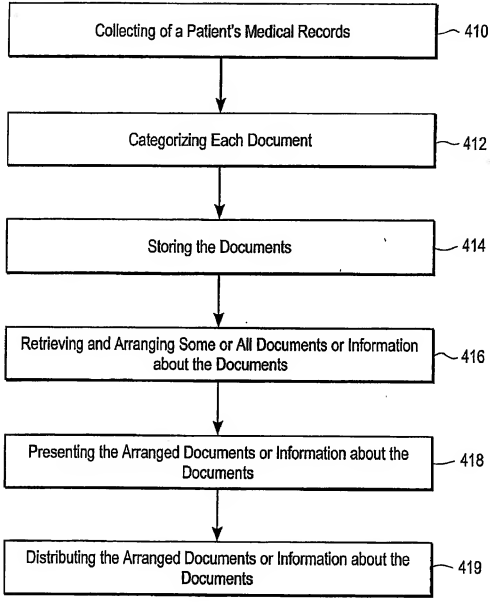

Collecting of a Patient's Medical Records
410
Categorizing Each Document
412
Storing the Documents
414
Retrieving and Arranging Some or All Documents or Information about the Documents
416
Presenting the Arranged Documents or Information about the Documents
418
Distributing the Arranged Documents or Information about the Documents
419

FIG. 6

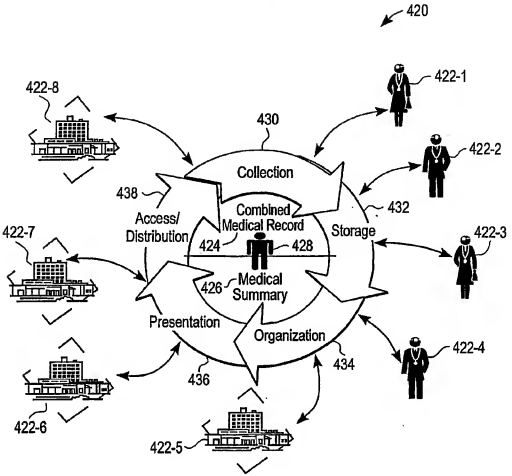

420
422-8
422-1
430
422-2
Collection
438
Access/
Distribution
Combined
Medical Record
424
428
432
Storage
422-7
422-3
426
Medical
Summary
Presentation
Organization
422-4
436
434
422-6
422-5

FIG. 7

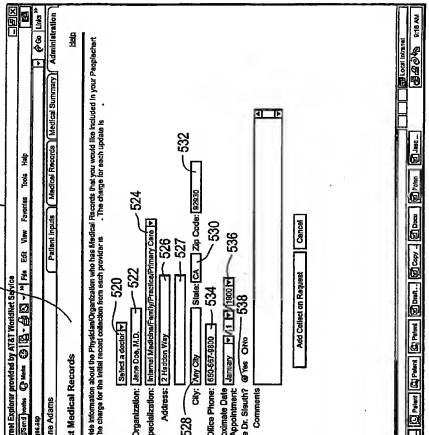

510
512
Administration Page - Microsoft Internet Explorer provided by AT&T WorldNet Service
Address http://telfer/peopleart/Adm/Pages.asp
PEOPLEMART
Collect Medical Records
Patient Inputs
Medical Records
Medical Summary
Administration
Help
Please provide information about the Physician/Organization who has Medical Records that you would like included in your Peoplechart database. The change for the initial record collection item provider is . The change for each update is .
Change Password
Change Physician Data
User Administration
Create/Query Access
Collect Records
Logout
Physician/Organization:
Specialization:
Address:
City:
Office Phone:
Approximate Date of First Appointment:
Use Dr. Sleuth?
Comments:
Shared a doctor?
John Doe, M.D.
Internal Medicine/Family Practice/Primary Care
2 Horizon Way
Any City
State:
CA
Zip Code:
90630
555-867-5309
January
1
1980
Yes
Ohno
Add Called on Request
Cancel
520
522
524
526
527
528
530
532
534
536
538

FIG. 8

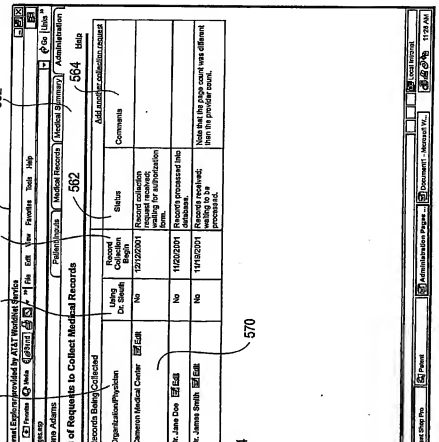

566
568
560
550
562
Administration Page - Microsoft Internet Explorer provided by AT&T Wireless Service
Address
PEOPLECHART
Mary Jane Adams
Patient Info
Medical Records
Medical Summary
Administration
Status of Requests to Collect Medical Records
564
Medical Records Being Collected
Add another collection request
Change Password
Change Credit Card
User Administration
Add Physician Access
Called Records
Logout
Request ID
Organization/Physician
Using Dr. Sheet
Record Collection Begin
Status
Comments
181
Cameron Medical Center
Edit
No
12/12/2001
Record collection request sent and waiting for authorization form.
113
Dr. Jane Doe
Edit
No
11/02/2001
Records processed into folder.
111
Dr. James Smith
Edit
No
11/16/2001
Records received, waiting to be processed.
Note that the page could vary different than the provider count.
554
570

FIG. 9

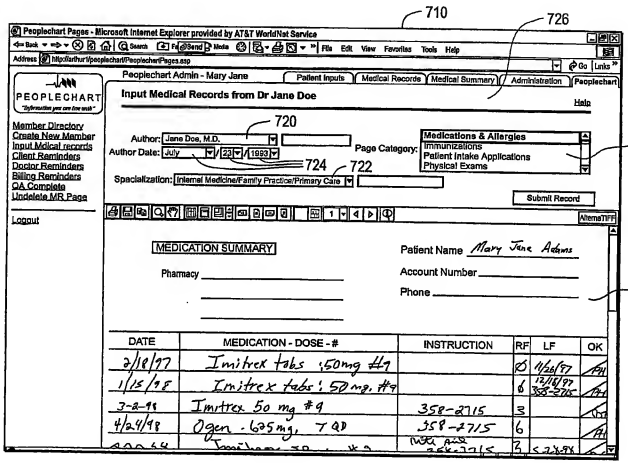
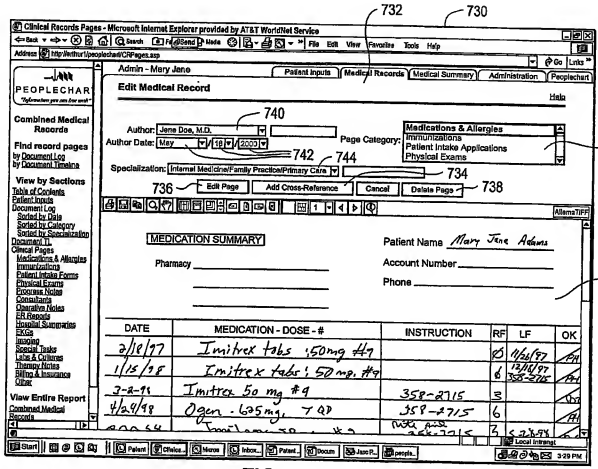

710
726
Peoplechart Pages - Microsoft Internet Explorer provided by AT&T WorldNet Service
File Edit View Favorites Tools Help
Address http://arthur/peoplechart/PeopleChartPages.asp
Go Links
PEOPLECHART
"Information you can live with."
Peoplechart Admin - Mary Jane
Patient Inputs
Medical Records
Medical Summary
Administration
Peoplechart
Input Medical Records from Dr Jane Doe
Help
720
Member Directory
Create New Member
Input Medical records
Client Reminders
Doctor Reminders
Billing Reminders
QA Complete
Undelete MR Page
Logout
Author: Jane Doe, M.D.
Author Date: July 22 1993
724
722
Page Category:
Medications & Allergies
Immunizations
Patient Intake Applications
Physical Exams
712
Specialization: Internal Medicine/Family Practice/Primary Care
Submit Record
AlternaTIFF
MEDICATION SUMMARY
Patient Name Mary Jane Adams
Pharmacy
Account Number
Phone
714
DATE
MEDICATION - DOSE - #
INSTRUCTION
RF
LF
OK
2/18/97 Imitrex tabs .50mg #9 0 11/26/97 AH
1/15/98 Imitrex tabs .50mg. #9 6 12/16/97 358-2715 AH
3-2-98 Imitrex 50 mg #9 358-2715 3 AH
4/24/98 Ogen .625mg. 1 QD 358-2715 6 AH

FIG. 10A


732
730
Clinical Records Pages - Microsoft Internet Explorer provided by AT&T WorldNet Service
Admin - Mary Jane
Patient Inputs
Medical Records
Medical Summary
Administration
Peoplechart
PEOPLECHAR
Edit Medical Record
Help
Combined Medical Records
Find record pages by Document Log by Document Timeline
View by Sections
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Sorted by Date
Sorted by Category
Sorted by Specialization
Document Tr.
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Immunizations
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Progress Notes
Consultants
Operative Notes
ER Records
Hospital Summaries
EKGs
Imaging
Special Tasks
Labs & Cultures
Therapy Notes
Billing & Insurance
Other
View Entire Report
Combined Medical Records
740
Author: Jane Doe, M.D.
Author Date: May 18 2000
742
Page Category:
Medications & Allergies
Immunizations
Patient Intake Applications
Physical Exams
746
744
Specialization: Internal Medicine/Family Practice/Primary Care
734
736
Edit Page
Add Cross-Reference
Cancel
Delete Page
738
AllenaTIFF
MEDICATION SUMMARY
Patient Name Mary Jane Adams
Pharmacy
Account Number
Phone
714
DATE
MEDICATION - DOSE - #
INSTRUCTION
RF
LF
OK
2/2/97 Imitrex tabs 50mg #9 8 1/26/97
1/15/98 Imitrex tabs 50 mg. #9 6 12/16/97
3-3-98 Imitrex 50 mg #9 358-2715 3
4/2/98 Ogen .625mg. 1 QD 358-2715 6
Local Intranet
3:29 PM

FIG. 10B

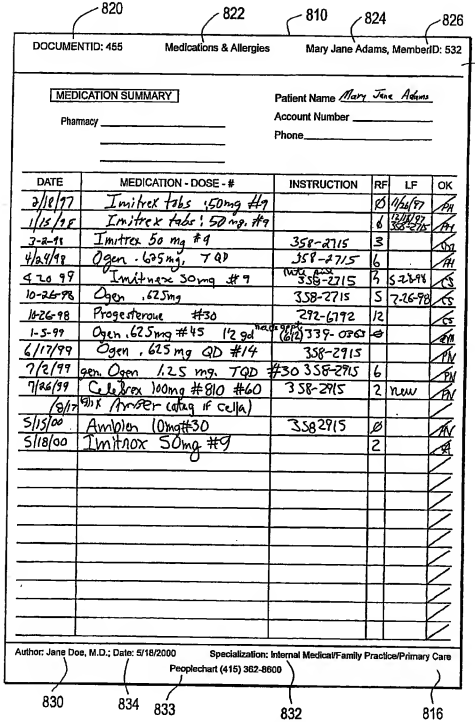

820
822
810
824
826
DOCUMENTID: 455
Medications & Allergies
Mary Jane Adams, MemberID: 532
814
MEDICATION SUMMARY
Patient Name Mary Jane Adams
Pharmacy
Account Number
Phone
DATE
MEDICATION - DOSE - #
INSTRUCTION
RF
LF
OK
3/18/97 Imitrex tabs ;50mg #9 0 4/24/97 PN
1/15/98 Imitrex tabs ; 50 mg. #9 6 12/10/97 PN
7-2-98 Imitrex 50 mg #9 358-2715 3 JDM
4/29/98 Ogen . 625mg, 1 QD 358-2715 6 PN
5-20-98 Imitrex 50mg #9 358-2715 3 5-22-98 JDM
10-26-98 Ogen .625mg 358-2715 5 7-26-98 CS
10-26-98 Progesterone #30 292-6192 12 CS
1-5-99 Ogen .625mg #45 1/2 qd (612) 338-0263 6 PN
6/17/99 Ogen . 625 mg QD #14 358-2915 PN
7/2/99 gen Ogen 1.25 mg. TQD #30 358-2915 6 PN
7/26/99 Celebrex 100mg #810 #60 358-2915 2 new PN
(8/17 Elvis Presley called in Cella)
5/15/00 Amplen 10mg#30 3582915 0 PN
5/18/00 Imitrex 50mg #9 2 PN
Author: Jane Doe, M.D.; Date: 5/18/2000
Specialization: Internal Medical/Family Practice/Primary Care
Peoplechart (415) 362-8600
830
834
833
832
816

FIG. 11

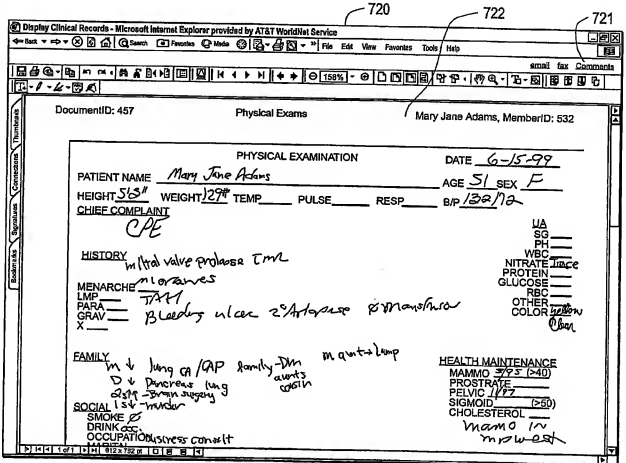

720
722
721
Display Clinical Records - Microsoft Internet Explorer provided by AT&T WorldNet Service
File Edit View Favorites Tools Help
email fax Comments
DocumentID: 457
Physical Exams
Mary Jane Adams, MemberID: 532
Favorites Signature Comments Thumbnails
PHYSICAL EXAMINATION
DATE 6-15-99
PATIENT NAME Mary Jane Adams
AGE 51 SEX F
HEIGHT 5'5" WEIGHT 129# TEMP PULSE RESP B/P 130/72
CHIEF COMPLAINT
CPE
HISTORY
Initial valve prolapse TMR
MENARCHE
LMP
PARA
GRAV
X
UA
SG
PH
WBC
NITRATE trace
PROTEIN
GLUCOSE
RBC
OTHER
COLOR
FAMILY
SOCIAL
SMOKE
DRINK
OCCUPATION
HEALTH MAINTENANCE
MAMMO
PROSTRATE
PELVIC
SIGMOID
CHOLESTEROL

FIG. 12

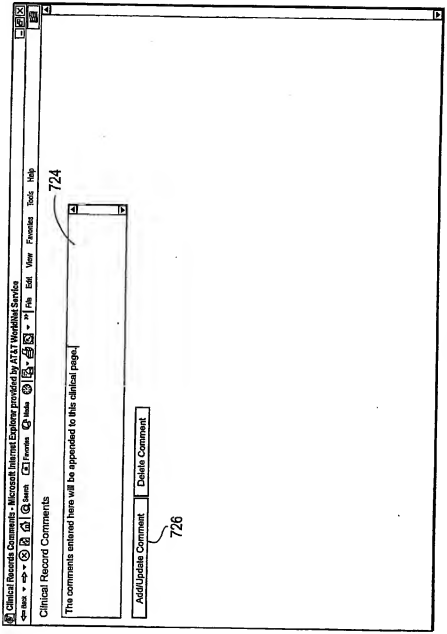

Clinical Records Comments - Microsoft Internet Explorer provided by AT&T Worldnet Service
File Edit View Favorites Tools Help
Back Search Favorites Media
Clinical Record Comments
The comments entered here will be appended to this clinical page.
724
Add/Update Comment
Delete Comment
726

FIG. 13

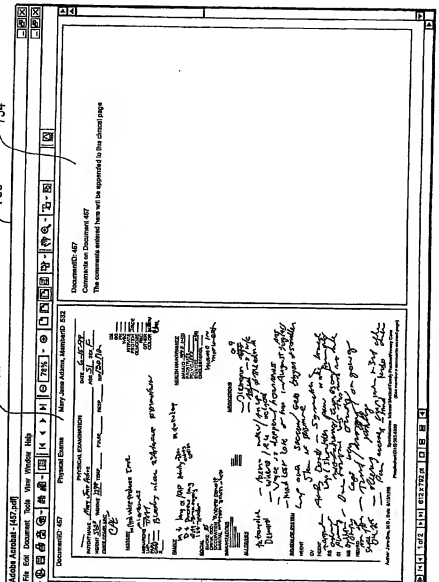
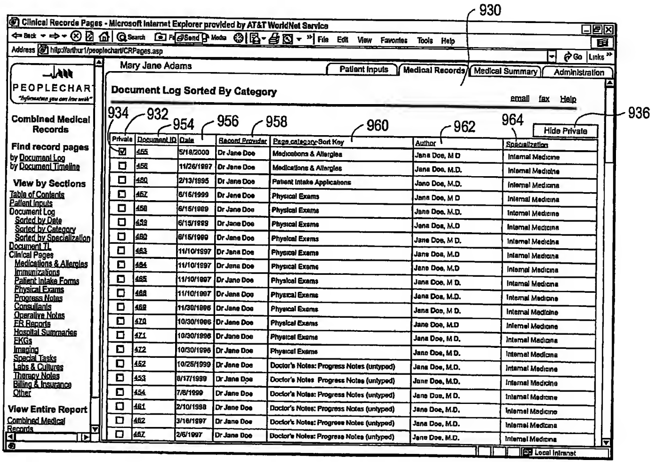

732
730
734
Adobe Acrobat - [457.pdf]
File Edit Document Tools View Window Help
Thumbnails
Comments
Signatures
Document ID: 457
Physical Exams
Mary Jane Adams, Member ID: 552
Document ID: 457
Comments entered here on Document 457
The comments entered here will be appended to the clinical page

FIG. 14

912 914 916 918 910 920 922

CLASSIFICATIONS OF PAGE TYPE (BY MEDICAL CATEGORY)					
	CMR	Timeline	MS		
Index ID	Sub-Sections	Sections	Sub-Sections	Description	Codes
1	1	1	1	Medications & Allergies	MED
2	1	1	1	Medication Refills & Logs	REF
3	2	2	2	Immunizations	IMU
4	3	3	NM	Patient Intake Forms	PIF
5	4	4	3	Physical Exams	PHX
6	5	5	4	Progress Notes-Outpatient (typed)	PN1
7	5	5	4	Progress Notes-Outpatient (untyped)	PN0
8	6	6	5	Consultants-Outpatient (typed)	CN1
9	6	6	5	Consultants-Outpatient (untyped)	CN0
10	7	7	6	Operative Notes	SUR
11	8	8	7	ER Reports	ERR
12	9	9	8	Hospital Summaries: Discharge Summary	HDS
13	9	9	8	Hospital Summaries: Admitting History & Physical	HHP
14	9	9	8	Hospital Summaries: Consultants-Inpatient	HCN
15	9	9	8	Hospital Summaries: Progress Notes-Inpatient	HPN
16	9	9	8	Hospital Summaries: Other	HOT
17	10	10	9	EKGs	EKG
18	11	11	10	Imaging: X-rays or Radiologic	XRY
19	11	11	10	Imaging: MRI	MRI
20	11	11	10	Imaging: Ultrasounds	UTR
21	11	11	10	Imaging: CAT or CT scans	CAT
22	11	11	10	Imaging: Mammograms	MAM
23	11	11	10	Imaging: Other	IOT
24	12	12	11	Special Tests	SPT
25	13	13	12	Labs & Cultures: CBC &/or Chemistry	LBC
26	13	13	12	Labs & Cultures: Protime	LPR
27	13	13	12	Labs & Cultures: Other	LOT
28	14	14	13	Therapy Notes	THR
29	15	15	NM	Billing & Insurance	BIN
30	16	CM	NM	Other: Administration	OAD
31	16	CM	NM	Other: Record Release	ORR
32	16	CM	NM	Other: Title Pages	OTP
33	16	CM	NM	Other: Duplicate Pages	ODP
34	16	CM	NM	Other: Irrelevant Pages	OIR
35	16	CM	NM	Other: Unclassified Pages	OUN

FIG. 15


930
Clinical Records Pages - Microsoft Internet Explorer provided by AT&T WorldNet Service
Back Search Send Media File Edit View Favorites Tools Help
Address http://arthur1/peoplechart/CRPages.asp
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PEOPLECHAR
Combined Medical Records
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by Document Timeline
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Imaging
Special Tasks
Labs & Cultures
Therapy Notes
Billing & Insurance
Other
View Entire Report
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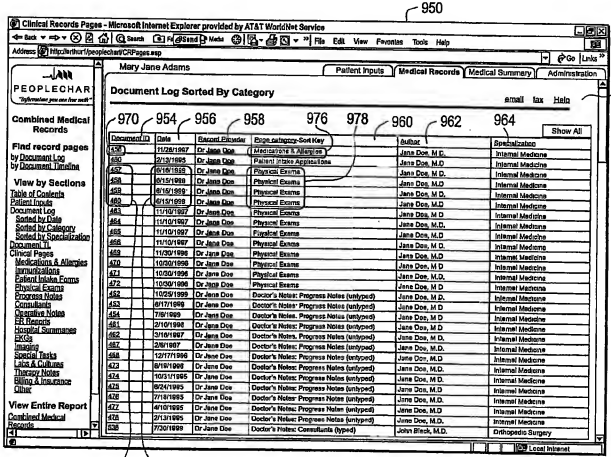
email fax Help
934
932
954
956
958
960
962
964
936
Hide Private
Private
Document ID
Date
Record Provider
Page category-Sort Key
Author
Specialization
455 5/18/2000 Dr Jane Doe Medications & Allergies Jane Doe, M D Internal Medicine
456 11/26/1997 Dr Jane Doe Medications & Allergies Jane Doe, M.D. Internal Medicine
480 2/13/1995 Dr Jane Doe Patient Intake Applications Jane Doe, M.D. Internal Medicine
457 6/16/1999 Dr Jane Doe Physical Exams Jane Doe, M D Internal Medicine
458 6/15/1999 Dr Jane Doe Physical Exams Jane Doe, M.D. Internal Medicine
459 6/15/1999 Dr Jane Doe Physical Exams Jane Doe, M.D Internal Medicine
460 6/15/1999 Dr Jane Doe Physical Exams Jane Doe, M D. Internal Medicine
463 11/10/1997 Dr Jane Doe Physical Exams Jane Doe, M.D Internal Medicine
464 11/10/1997 Dr Jane Doe Physical Exams Jane Doe, M.D Internal Medicine
465 11/10/1997 Dr Jane Doe Physical Exams Jane Doe, M D. Internal Medicine
468 11/10/1997 Dr Jane Doe Physical Exams Jane Doe, M.D. Internal Medicine
469 11/30/1996 Dr Jane Doe Physical Exams Jane Doe, M D. Internal Medicine
470 10/30/1996 Dr Jane Doe Physical Exams Jane Doe, M.D Internal Medicine
471 10/30/1996 Dr Jane Doe Physical Exams Jane Doe, M D. Internal Medicine
472 10/30/1996 Dr Jane Doe Physical Exams Jane Doe, M D. Internal Medicine
452 10/25/1999 Dr Jane Doe Doctor's Notes: Progress Notes (untyped) Jane Doe, M.D. Internal Medicine
453 8/17/1999 Dr Jane Doe Doctor's Notes Progress Notes (untyped) Jane Doe, M.D. Internal Medicine
454 7/8/1999 Dr Jane Doe Doctor's Notes: Progress Notes (untyped) Jane Doe, M D. Internal Medicine
461 2/10/1998 Dr Jane Doe Doctor's Notes: Progress Notes (untyped) Jane Doe, M.D. Internal Medicine
462 3/16/1997 Dr Jane Doe Doctor's Notes: Progress Notes (untyped) Jane Doe, M.D. Internal Medicine
467 2/6/1997 Dr Jane Doe Doctor's Notes: Progress Notes (untyped) Jane Doe, M.D. Internal Medicine
Local Intranet

FIG. 16


950
Clinical Records Pages - Microsoft Internet Explorer provided by AT&T WorldNet Service
Mary Jane Adams
Patient Inputs
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Administration
PEOPLECHAR
Combined Medical Records
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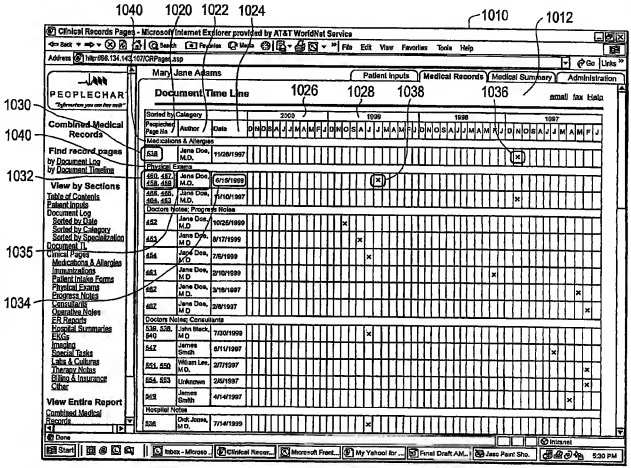
Consultants
Operative Notes
ER Reports
Hospital Summaries
ECGs
Imaging
Special Tasks
Labs & Cultures
Therapy Notes
Billing & Insurance
Other
View Entire Report
Combined Medical Records
Document Log Sorted By Category
email fax Help
952
Show All
970 954 956 958 976 978 960 962 964
Document ID | Date | Record Provider | Page category-Sort Key | Author | Specialization
638 | 11/26/1997 | Dr Jane Doe | Medications & Allergies | Jane Doe, M.D. | Internal Medicine
650 | 2/13/1995 | Dr Jane Doe | Patient Intake Applications | Jane Doe, M.D | Internal Medicine
657 | 09/16/1998 | Dr Jane Doe | Physical Exams | Jane Doe, M.D. | Internal Medicine
658 | 9/15/1999 | Dr Jane Doe | Physical Exams | Jane Doe, M.D | Internal Medicine
659 | 9/15/1999 | Dr Jane Doe | Physical Exams | Jane Doe, M.D. | Internal Medicine
660 | 9/15/1998 | Dr Jane Doe | Physical Exams | Jane Doe, M.D | Internal Medicine
663 | 11/10/1997 | Dr Jane Doe | Physical Exams | Jane Doe, M.D | Internal Medicine
664 | 11/10/1997 | Dr Jane Doe | Physical Exams | Jane Doe, M.D. | Internal Medicine
668 | 11/10/1997 | Dr Jane Doe | Physical Exams | Jane Doe, M.D | Internal Medicine
666 | 11/10/1997 | Dr Jane Doe | Physical Exams | Jane Doe, M.D. | Internal Medicine
669 | 11/20/1996 | Dr Jane Doe | Physical Exams | Jane Doe, M.D | Internal Medicine
670 | 10/20/1998 | Dr Jane Doe | Physical Exams | Jane Doe, M.D | Internal Medicine
671 | 10/20/1996 | Dr Jane Doe | Physical Exams | Jane Doe, M.D. | Internal Medicine
672 | 10/20/1998 | Dr Jane Doe | Physical Exams | Jane Doe, M.D | Internal Medicine
652 | 10/25/1999 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D. | Internal Medicine
653 | 8/17/1998 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D | Internal Medicine
654 | 7/9/1999 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D | Internal Medicine
661 | 2/10/1998 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D | Internal Medicine
662 | 5/10/1997 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D. | Internal Medicine
667 | 2/9/1997 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D. | Internal Medicine
668 | 12/17/1996 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D | Internal Medicine
673 | 8/19/1998 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D. | Internal Medicine
674 | 10/31/1995 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D. | Internal Medicine
675 | 9/24/1995 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D | Internal Medicine
676 | 7/19/1995 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D. | Internal Medicine
677 | 4/10/1995 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D | Internal Medicine
678 | 2/13/1995 | Dr Jane Doe | Doctor's Notes: Progress Notes (untyped) | Jane Doe, M.D. | Internal Medicine
636 | 7/30/1999 | Dr Jane Doe | Doctor's Notes: Consultants (typed) | John Black, M.D. | Orthopedic Surgery
Local Intranet
972 974

FIG. 17


1040
1020
1022
1024
1010
1012
1030
1040
1032
1035
1034
1026
1028
1038
1036
Clinical Records Pages - Microsoft Internet Explorer provided by AT&T WorldNet Service
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email fax Help
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Imaging
Special Tasks
Labs & Cultures
Therapy Notes
Billing & Insurance
Other
View Entire Report
Combined Medical Records
Sorted by Category
Pagelet/ Page No
Author
Date
2000
1999
1998
1997
Medications & Allergies
Physical Exams
Doctors Notes: Progress Notes
Doctors Notes: Consultants
Hospital Notes
Jane Doe, M.D.
6/15/1999
Jane Doe, M.D.
5/10/1997
Jane Doe, M.D.
10/25/1999
Jane Doe, M.D.
8/17/1999
Jane Doe, M.D.
7/5/1999
Jane Doe, M.D.
2/10/1999
Jane Doe, M.D.
3/18/1997
Jane Doe, M.D.
2/9/1997
John Black, MD
7/30/1999
James Smith
8/11/1997
William Lee, M.D.
2/7/1997
Unknown
2/5/1997
James Smith
4/14/1997
Dick Jones, M.D.
7/14/1999
Done
Internet
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Inbox - Microso...
Clinical Recor...
Microsoft Front...
My Yahoo! for ...
Final Draft AM...
Jass Pent Sho...
5:30 PM

FIG. 18

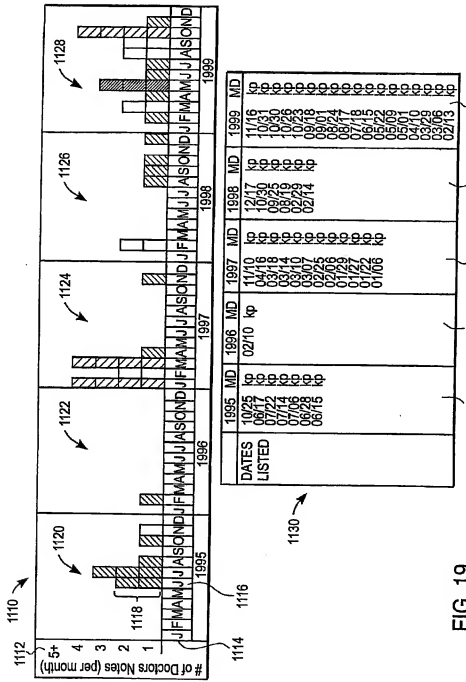
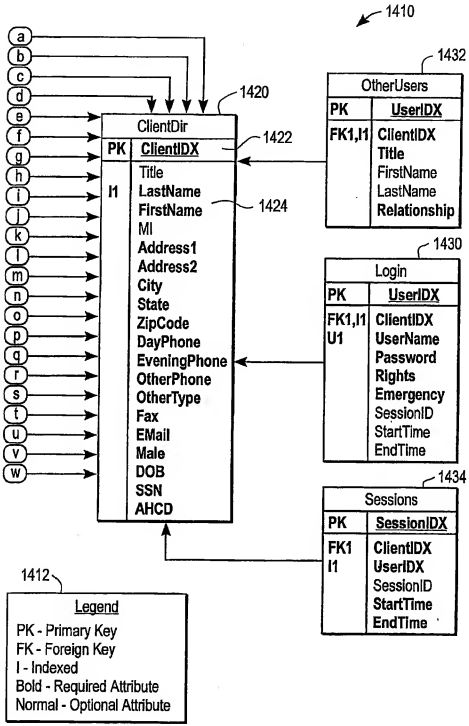

1110
1112
# of Doctors Notes (per month)
5+
4
3
2
1
1114
1116
1118
1120
1122
1124
1126
1128
J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D
1995
1996
1997
1998
1999
1130
DATES LISTED
1995 MD
10/25 kp
06/17
07/22
07/14 kp
07/06 kp
06/28 kp
06/15 kp
1996 MD
02/10 kp
1997 MD
11/10 kp
04/18 kp
03/18 kp
03/14 kp
03/10 kp
03/07 kp
02/25 kp
01/29 kp
01/27 kp
01/22 kp
01/06 kp
1998 MD
12/17 kp
10/29 kp
08/19 kp
02/25 kp
02/14 kp
1999 MD
11/16 kp
10/31 kp
10/30 kp
10/23 kp
09/18 kp
09/01 kp
08/24 kp
07/18 kp
06/15 kp
05/22 kp
05/09 kp
05/01 kp
03/29 kp
03/06 kp
02/13 kp
1132
1134
1136
1138
1140

FIG. 19


1410
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d
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f
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p
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r
s
t
u
v
w
1420
ClientDir
PK ClientIDX
1422
I1 Title
LastName
FirstName
1424
MI
Address1
Address2
City
State
ZipCode
DayPhone
EveningPhone
OtherPhone
OtherType
Fax
EMail
Male
DOB
SSN
AHCD
1432
OtherUsers
PK UserIDX
FK1,I1 ClientIDX
Title
FirstName
LastName
Relationship
1430
Login
PK UserIDX
FK1,I1 ClientIDX
U1 UserName
Password
Rights
Emergency
SessionID
StartTime
EndTime
1434
Sessions
PK SessionIDX
FK1 ClientIDX
I1 UserIDX
SessionID
StartTime
EndTime
1412
Legend
PK - Primary Key
FK - Foreign Key
I - Indexed
Bold - Required Attribute
Normal - Optional Attribute

FIG. 20-1

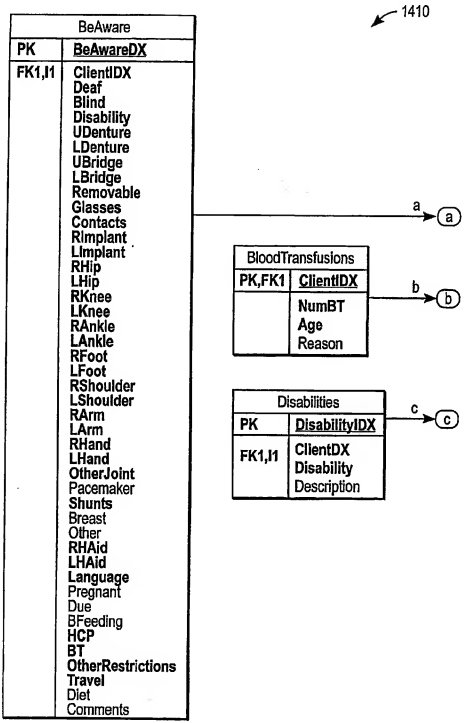

1410
BeAware
PK
BeAwareDX
FK1,I1
ClientIDX
Deaf
Blind
Disability
UDenture
LDenture
UBridge
LBridge
Removable
Glasses
Contacts
RImplant
LImplant
RHip
LHip
RKnee
LKnee
RAnkle
LAnkle
RFoot
LFoot
RShoulder
LShoulder
RArm
LArm
RHand
LHand
OtherJoint
Pacemaker
Shunts
Breast
Other
RHAid
LHAid
Language
Pregnant
Due
BFeeding
HCP
BT
OtherRestrictions
Travel
Diet
Comments
a
a
BloodTransfusions
PK,FK1
ClientIDX
NumBT
Age
Reason
b
b
Disabilities
PK
DisabilityIDX
FK1,I1
ClientDX
Disability
Description
c
c

FIG. 20-2

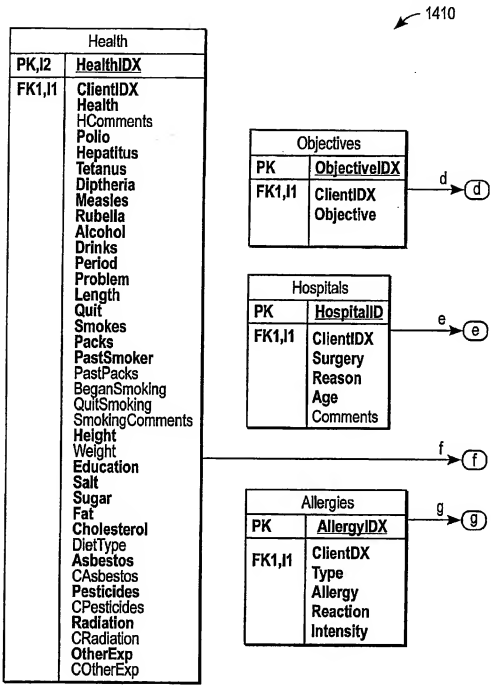

1410
Health
PK,I2
HealthIDX
FK1,I1
ClientIDX
Health
HComments
Polio
Hepatitus
Tetanus
Diptheria
Measles
Rubella
Alcohol
Drinks
Period
Problem
Length
Quit
Smokes
Packs
PastSmoker
PastPacks
BeganSmoking
QuitSmoking
SmokingComments
Height
Weight
Education
Salt
Sugar
Fat
Cholesterol
DietType
Asbestos
CAsbestos
Pesticides
CPesticides
Radiation
CRadiation
OtherExp
COtherExp
Objectives
PK
ObjectiveIDX
FK1,I1
ClientIDX
Objective
d
d
Hospitals
PK
HospitalID
FK1,I1
ClientIDX
Surgery
Reason
Age
Comments
e
e
f
f
Allergies
PK
AllergyIDX
FK1,I1
ClientDX
Type
Allergy
Reaction
Intensity
g
g

FIG. 20-3

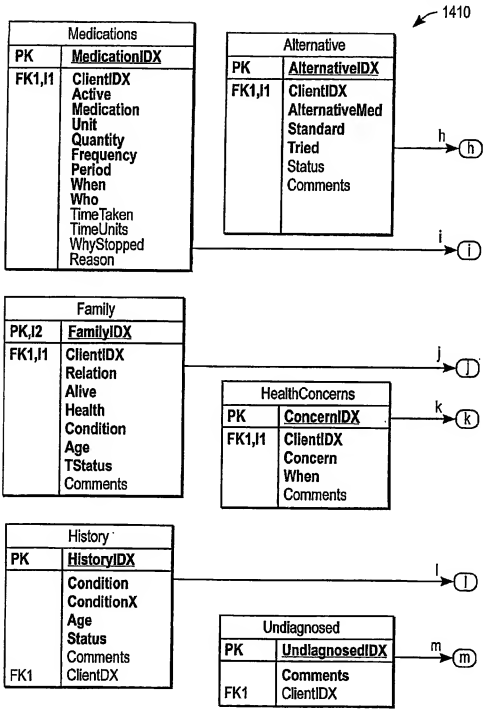
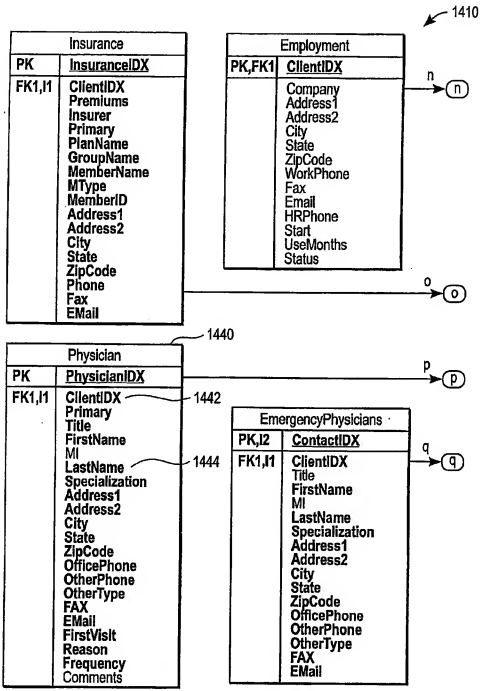

1410
Medications
PK MedicationIDX
FK1,I1 ClientIDX
Active
Medication
Unit
Quantity
Frequency
Period
When
Who
TimeTaken
TimeUnits
WhyStopped
Reason
Alternative
PK AlternativeIDX
FK1,I1 ClientIDX
AlternativeMed
Standard
Tried
Status
Comments
h
h
i
i
Family
PK,I2 FamilyIDX
FK1,I1 ClientIDX
Relation
Alive
Health
Condition
Age
TStatus
Comments
j
j
HealthConcerns
PK ConcernIDX
FK1,I1 ClientIDX
Concern
When
Comments
k
k
History
PK HistoryIDX
Condition
ConditionX
Age
Status
Comments
FK1 ClientDX
l
l
Undiagnosed
PK UndiagnosedIDX
Comments
FK1 ClientIDX
m
m

FIG. 20-4


1410
Insurance
PK
InsuranceIDX
FK1,I1
ClientIDX
Premiums
Insurer
Primary
PlanName
GroupName
MemberName
MType
MemberID
Address1
Address2
City
State
ZipCode
Phone
Fax
EMail
Employment
PK,FK1
ClientIDX
Company
Address1
Address2
City
State
ZipCode
WorkPhone
Fax
Email
HRPhone
Start
UseMonths
Status
n
o
1440
Physician
PK
PhysicianIDX
FK1,I1
ClientIDX
Primary
Title
FirstName
MI
LastName
Specialization
Address1
Address2
City
State
ZipCode
OfficePhone
OtherPhone
OtherType
FAX
EMail
FirstVisit
Reason
Frequency
Comments
1442
1444
p
EmergencyPhysicians
PK,I2
ContactIDX
FK1,I1
ClientIDX
Title
FirstName
MI
LastName
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Address1
Address2
City
State
ZipCode
OfficePhone
OtherPhone
OtherType
FAX
EMail
q

FIG. 20-5

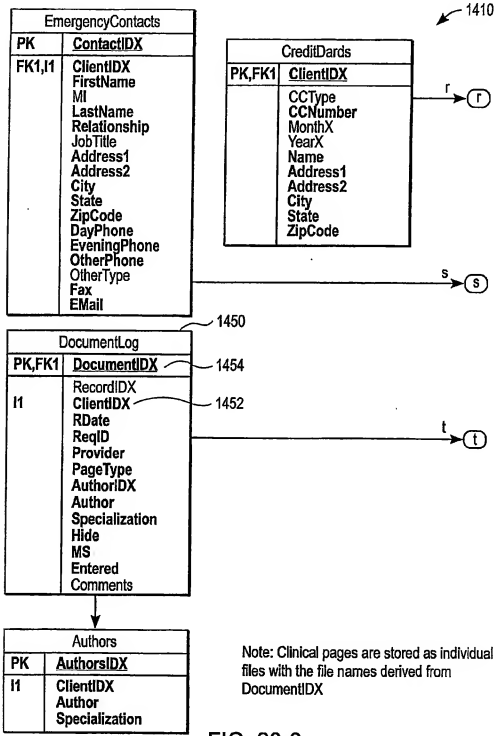
1410
EmergencyContacts
PK
ContactIDX
FK1,I1
ClientIDX
FirstName
MI
LastName
Relationship
JobTitle
Address1
Address2
City
State
ZipCode
DayPhone
EveningPhone
OtherPhone
OtherType
Fax
EMail
CreditDards
PK,FK1
ClientIDX
CCType
CCNumber
MonthX
YearX
Name
Address1
Address2
City
State
ZipCode
r
s
1450
DocumentLog
PK,FK1
DocumentIDX
1454
RecordIDX
I1
ClientIDX
1452
RDate
ReqID
Provider
PageType
AuthorIDX
Author
Specialization
Hide
MS
Entered
Comments
t
Authors
PK
AuthorsIDX
I1
ClientIDX
Author
Specialization
Note: Clinical pages are stored as individual files with the file names derived from DocumentIDX

FIG. 20-6

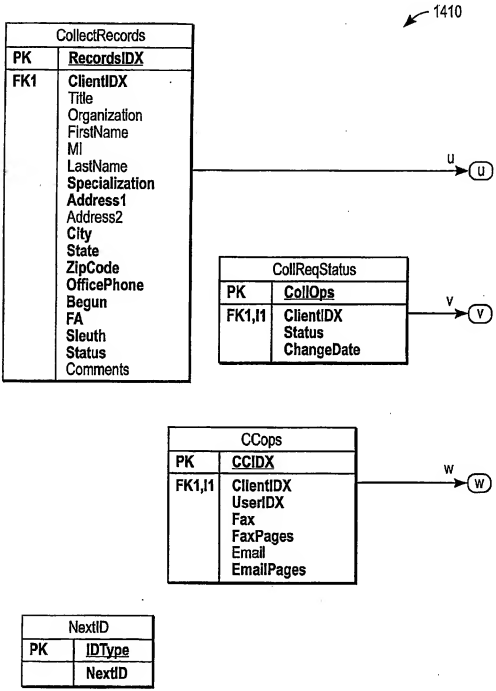
1410
CollectRecords
PK
RecordsIDX
FK1
ClientIDX
Title
Organization
FirstName
MI
LastName
Specialization
Address1
Address2
City
State
ZipCode
OfficePhone
Begun
FA
Sleuth
Status
Comments
U
U
CollReqStatus
PK
CollOps
FK1,I1
ClientIDX
Status
ChangeDate
V
V
CCops
PK
CCIDX
FK1,I1
ClientIDX
UserIDX
Fax
FaxPages
Email
EmailPages
W
W
NextID
PK
IDType
NextID

FIG. 20-7

PATIENT DIRECTED SYSTEM AND METHOD FOR MANAGING MEDICAL INFORMATION

[0001] This application claims priority from and incorporates by reference in its entirety U.S. Provisional Application Serial No. 60/349,883 titled "A System And Method For Managing Medical Information," filed Jan. 18, 2002.

FIELD OF THE INVENTION

[0002] The invention relates generally to the field of medical records management and in particular to the collection, organization, presentation, and distribution of a patient's medical records.

BACKGROUND OF THE INVENTION

[0003] Having a complete set of medical records significantly improves the quality of health care for a patient by establishing a patient's medical baseline and indicating patterns in the patient's medical history. Those records provide information impacted by time and by the diversity of medical view points and knowledge gained from clinical tests. Having a comprehensive set of data that goes back in time and that is inclusive of observations and findings from multiple providers who have seen or treated the patient over time makes a difference in the quality of the information used to accurately diagnose and treat medical problems. This is especially true for medical problems in the early stages of development. Patient records, when consolidated and complete, often show identifiable patterns of symptoms, diagnoses, treatments and responses to those treatments over the life of the patient. When new health issues arise, or an old one recurs, the information and patterns contained in the medical records can help guide health professionals in making new diagnoses and in their choices for treatments. Each patient's baseline medical information is unique. Many people exhibit unusual readings on some medical tests as part of their normal healthy baseline state, even though those same readings might be considered unhealthy when considered in isolation. In the context of the patient's past history, these unusual readings become part of the patient's baseline, and the repetition of those unusual readings over time is not a major concern. However, in the absence of the patient's historical baseline information, these unusual test results could provoke misunderstandings or over-reactions from doctor(s) not familiar with the patient's history. The risk of medical errors can be significantly reduced by providing patient-specific information to doctors currently diagnosing or treating the patient about the patient's adverse effects of past treatments, allergic reactions to certain drugs, and general disposition to certain diseases or health conditions. In addition, part of a patient's medical history can include their family medical history. Historical family records of medical conditions can help determine a patient's level or risks for certain medical conditions, such as heart disease, diabetes, and breast cancer, and can alert health care providers when increased screening and other tests are advisable.

[0004] In the past, when a patient generally had one or a handful of doctors for most of his life, the doctor(s) more often had records and knowledge of the patient's complete medical history. In today's world, a number of economic forces and trends in health care are contributing to the increasing fragmentation of patient records across multiple providers, and to increasing discontinuity in the knowledge of the patient's medical history by the patient's doctors over time. Examples of these trends include the increasing frequency with which patients change medical insurance and jobs, move residences, and are being referred to health care specialists. In addition, it is now more common for patients to consult with multiple doctors and specialists for treatment alternatives and second opinions. On the provider side of the health care industry, there is a growing trend toward increased specialization on the part of doctors. Also, in response to economic pressures and wide-spread disruptions in the health care industry caused by business insolvency, poor operating results, and by increasing frustrations with unpopular reimbursement policies and cost-cutting practices of hospitals, Health Maintenance Organizations (HMOs), and other health care groups, doctors have become more resolved to close practices or switch their allegiance to business practices and affiliations. When they do switch, patients often need to find new doctors or organizations to provide them care. Today's patient typically sees many more healthcare providers over his lifetime than was the case in previous generations.

[0005] Each healthcare provider is concerned with the maintenance and/or restoration of the health of the body and/or mind of the patient. The health care provider may be one person (e.g., sole practitioner), a group of persons (e.g., a family clinic), or an organization (e.g., hospital or medical university) that for legal and billing reasons, is the author, owner, and custodian of only that portion of a patient's medical records corresponding to the diagnosis or treatment that the healthcare provider provides to the patient. For today's patient, there is very seldom a single provider who would have all the records of the patient's other providers, past and present. Moreover, because patient's medical records are typically paper-based records, the healthcare provider incurs overhead costs in maintaining and storing them. This creates an economic incentive for each healthcare provider to try to minimize the records it keeps to only those records pertaining to the portion of the patient's care that the healthcare provider itself has provided. When the healthcare provider requires access to other portions of the patient's medical records (i.e., information about the patient authored by other healthcare providers), requesting-physicians typically only request and retrieve from these other health care providers medical records that are of immediate relevance to them. Hence only a subset, rather than a complete set, of a patient's medical records are kept by a health care provider in order to minimize the additional storage and other administrative costs. For the same economic reasons, a healthcare provider typically discards a patient's medical records, after the patient becomes inactive under that provider's care for a legally specified time, e.g., 5 to 7 years.

[0006] From the record sending side, there are problems in performing the transfer of medical records between healthcare providers. There is also an economic disincentive and therefore a reluctance or a slow reaction for the healthcare provider holding the patient's medical records to transfer copies of a patient's records to other providers because the costs of retrieval, copying, and mailing are traditionally born by the sending-physician as a common courtesy to the receiving-physician. To help keep these costs down, the tasks of administering, copying, and mailing record copies are often performed only during slow periods or during lulls in other activities of the medical office staff. The relatively

low priority assigned to providing copies of medical records often results in long delays between the request for and the delivery of patient records, even when disclosure is legally authorized and record copies required to be released.

[0007] Upon receipt, the receiving-providers often need to reorganize the paper records according to their own system of record-keeping. While the increased use of electronic medical records (EMRs) over paper-based records has reduced the storage cost, paper-based records are still prevalent. Over 80% of patients' medical record information still exist in paper formats. Doctors continue to make handwritten notes of their diagnoses and treatments. In addition, today when records are kept in electronic form in an Electronic Medical Record (EMR) system, records are still commonly transmitted between doctors in hard copy, paper-format. This is true even when both doctors have access to different EMR systems because such systems are rarely compatible with each other. When the transfer of patient information is between one computer application and another, the computer applications maintaining the electronic medical records typically differ between health care providers. So, if it is deemed necessary to convert paper records into electronic format for information consolidation and processing, the receiving-provider would have to bear the cost of converting records to electronic format, including record storage costs and the ongoing costs of creating scanned images of paper-based records. Rather than converting records from sending-providers into electronic format, or from sending-providers' electronic format to paper-based and then to the receiving-providers' electronic format, today's common practice is for recipient-providers to simply review the paper copies of records received and file them away with the rest of the patient's paper-based records providers.

[0008] Thus, because each healthcare provider typically keeps their own medical records of the patient and because there is little actual sharing or records between healthcare providers, the result is a fragmentation of a patient's medical records across the multiple healthcare providers. In effect each healthcare provider becomes a part of a puzzle of the patient's medical history, and no healthcare provider sees the whole picture. This fragmentation of information about the patient is further exacerbated by the patient's increasing use of specialists and increasing need to switch health insurance plans and healthcare providers in order to pursue better care or to reduce cost of the premium. The increase in providers seen in the context of little real sharing of patient's medical records across providers also results in increasing incidence of redundant tests and of treatments that are done in lieu of each new doctor have timely access to a patient's complete medical records. In addition, as the Institute of Medicine summarized in a 1999 report, lack of communication and information on patient medical conditions and history of drug reactions can be cited as a key reason that medical errors result in thousands of other-wise preventable deaths each year. On the provider side, there are economic pressures for providers to switch health affiliations due to poor business results or business insolvency of their current practice or affiliations or due to increasing frustration with reimbursement policies and cost-cutting practices of hospitals, HMOs and other health care groups.

[0009] FIG. 1 illustrates the fragmentation puzzle of a patient's medical records of the prior art. A patient has typically many healthcare providers over the patient's life, e.g., hospitals A and H, doctors B, C, D, and E, and other provides F and G (e.g., providers of Chiropractic or Homeopathic medicine). Doctors B and C illustrate hy overlap area 110 the case when two healthcare providers share some, but not all their medical records. If two healthcare providers share all their records then for the purposes of this application, they are considered to be the same healthcare provider. In addition a patient may keep her own files.

[0010] FIG. 2 is a block diagram of an example flow of a patient's medical records among different healthcare providers of the prior art, that results in the fragmentation puzzle of FIG. 1. FIG. 2 illustrates that a partial transfer, or in some cases no transfer, of a patient's records from one healthcare provider to another causes more and more fragmentation of a patient's medical history over a patient's lifetime. While in this example, for illustration purposes, medical records are described as transferred between health care providers, the records are actually transferred from one health care provider's medical record repository or filing system to another health care provider's medical record repository or filing system. In this example, a patient begins with a general practitioner 110, e.g., a pediatrician, when the patient was a child. The patient then has general practitioner 112 as an adult. General practitioner 112 thinking that it was too long ago, decides not to request past medical records from general practitioner 110 and instead relies on a patient interview to fill in the patient's medical history. As a patient's memory is often fuzzy and a poor substitute for clinical information, general practitioner 112 gets an incomplete picture of the patient's childhood medical history. General practitioner 112 may send the patient to a specialist 114, e.g., a surgeon for an appendectomy. The specialist 114 gets some of the patient's medical records from general practitioner 112 (path 113a) and may also request other historical records from general practitioner 110 (path 118). The specialist 114 creates her own records and transfers all or most of these initial records, but not all ongoing records, back to general practitioner 112 (path 113b). The patient continues to see the specialist 114, at times without the General Practitioner 112. The ongoing updates by the specialist 114, after the initial introduction, are usually not managed and so any new information accumulated on the patient would most likely not be communicated back to General Practitioner 112. General practitioner 112 meanwhile continues to add new records as he continues to care for the patient. When the patient moves to a new general practitioner 120, for example, because of moving, changing jobs or switching to a health plan to which general practitioner 112 is not affiliated, the new provider will need access to the patient's medical history. As illustrated, the possible paths for general practitioner 120 to get a complete set of medical records is becoming complex. To get a complete medical history of the patient, general practitioner 120 needs medical records from general practitioner 110 (path 131), general practitioner 112 (path 130) and specialist 114 (path 132). However, to reduce costs and because of the delay in getting the records, general practitioner 120 may only request some "needed" records from general practitioner 112 (path 130) and no records from general practitioner 110 (path 131) or specialist 114 (path 132). If general practitioner 120 refers the patient to specialist 122, then specialist 122 has many paths, i.e., 121a, 134, and from which he may need medical records. However, specialist 122 may, to cut

costs, only request the patient's medical records from general practitioner 120 (path 121a). Note that at this point no single provider necessarily has complete records on all patient medical care. Thus as this example indicates, as a patient goes from healthcare provider to healthcare provider, the patient's medical records often get more and more fragmented. Further, at some point, practitioners will discard the patient's medical records and vital information may be forever lost and will not be available at a critical time.

[0011] Several prior art systems have tried to solve the fragmentation problem by providing a centralized computer storage area available to the patient for storage of some of a patient's medical records. However, these prior art systems only store a small subset of a patient's medical history. Most examples of these prior art systems are Electronic Medical Record (EMR) systems that have scope and function limited to the portion of the patient's records corresponding to only that provider's care. One system allows a patient or his doctor to fax in to the central repository copies of the patient's medical records under their control. Some minimal organization of the scanned images is done manually by the patient, e.g., putting certain images in a patient's emergency folder and the rest in a general folder. As the number of images gets large, this very limited organization of the scanned images does not allow for timely retrieval of a relevant subset by a doctor currently treating a patient. In addition, because the patient, not a medical records technician, medical professional, or health service entity, selects what is to be placed in the emergency folder, some of relevant data may be omitted. Thus this system has both the disadvantages of a very incomplete patient history and limited usefulness of the images because the patient is forced to make decisions about the relevancy of certain medical information.

[0012] A patient's health is best served by a complete or nearly complete set of medical records with a comprehensive organizational structure used throughout. In contrast, prior art systems only provide a small subset of the patient's medical records within organizational structures that are likely to be inadequate to the needs and the time pressures of a healthcare provider currently diagnosing and treating the patient: the vast majority of the patient's medical records remain fragmented over the rest of the patient's many past and present healthcare providers. Prior art systems which provide the ability to consolidate a patient's medical records from the past do not provide meaningful or comprehensive organization for the patient's consolidated medical records. What is needed is a method and system that manages a complete or nearly complete set of a patient's medical records that allows easy retrieval and meaningful display of relevant information.

SUMMARY OF THE INVENTION

[0013] The present invention includes a system and a method for the collection, organization, and distribution of a patient's medical records by a central data repository under the direction of the patient. Medical records from a plurality of the patient's healthcare providers, including past and present healthcare providers, are maintained in this central repository, thus providing a comprehensive, organized, and accessible medical history of a patient.

[0014] An exemplary embodiment has a patient-directed central data repository and a set of processes that enable the patient to be the hub in a hub-and-spoke arrangement, where each spoke goes to one of the patient's healthcare providers, both past and present. The patient's medical records, past and present, and any updates thereunto, from one or more of the patient's healthcare providers are collected, classified and stored in the central data repository At the patient's authorization, healthcare providers can gain access to the central repository and view the patient's consolidated medical records. The system which stores the records in the central data repository provides classification schema and capabilities that enable the record pages to be sorted and prioritized in numerous meaningful ways. The sorted medical records and descriptive information about the entire record collection can be displayed to both the patient and/or the healthcare provider currently advising and/or treating the patient and/or other entities designated by the patient. The system also automatically organizes the medical record documents in such a way that facilitates the generation of reports that can then be readily distributed via fax, email, hardcopy and/or CD-ROM to the patient or patient's designated entities.

[0015] One embodiment of the present invention includes a method for organizing patient's medical records authored by multiple healthcare providers. Two or more documents, comprising part of the patient's medical records, are categorized according to a categorization system and stored in a storage area of a central repository, where access to the central storage area must be authorized by the patient. An ordered set of the categorized documents is retrieved from the central storage area using at least one criterion of a plurality of predetermined criteria. In addition the ordered set may be displayed via a Web browser or distributed in hard copy format.

[0016] Another embodiment of the present invention includes a method for selecting and sorting two or more documents from the patient's complete medical records according to selected document categories and various sort criteria. In addition, the sorted documents can be displayed via a Web browser rather than distributed via fax, email or hard copy format]

[0017] Another embodiment of the present invention includes a method for a patient accessing his/her own medical records originated from multiple healthcare providers. First, the documents of the patient's medical records are collected from both past and present healthcare providers. The documents are then categorized according to a categorization system having more than two categories and stored in a central storage area on a computer system, where the storage area is under direct or indirect control of the patient. An example of indirect control is a service provider that directly controls the central storage area, but is directed by the patient, or the patient's legal representative, on what information can be viewed and accessed and by whom. Lastly, a document is retrieved from the storage area according to a selection criterion, where the selection criterion is based on the categorization system. Optionally, the selected document is displayed to the patient or the patient distributes the document via fax or email or directs a service provider to distribute the document via fax, email, or send in hard-copy or CD-ROM format through traditional mail.

[0018] An aspect of the present invention, includes a method for a patient accessing his/her medical records

originated by multiple healthcare providers. First, the patient's medical records are collected from the healthcare providers. Next, documents of the patient's medical records are categorized according to a categorization system, and the categorized documents are stored in the patient directed central computer storage area. A document log of some or all of the categorized documents is then displayed to the patient.

[0019] Another aspect of the present invention includes a system for centrally managing a patient's medical records originating from multiple healthcare providers. The system includes: a collection service module for collecting the patient's medical records from the healthcare providers; a computerized categorization system for categorizing each medical record, where the categorization system is the same for all of the patient's healthcare providers; a patient directed central computer storage area for storing the categorized medical records; and a retrieval module for retrieving ordered or sorted documents, where the ordered documents are arranged using at least one criterion of two or more criteria, where the criteria are based on the computerized categorization system.

[0020] Another embodiment of the present invention includes a method of centrally managing a patient's medical records originated by multiple healthcare providers. First, the patient's medical records, including paper-based documents, are collected from the patient's past and present healthcare providers. Next, each page of the paper-based documents is classified using classes of a classification system common across all the patient's healthcare providers. Each page of the paper-based documents is converted to an electronic image and stored in a computer readable medium, where third party access to the computer readable medium is authorized by the patient or his legal representative. An organized subset of said electronic images is retrieved using at least one selection criterion of a plurality of selection criteria, and displayed to a patient designated entity.

[0021] In yet another embodiment of the present invention a system for centrally managing patient's medical records originated by multiple healthcare providers is provided. The system includes: a backend server for receiving the patient's medical records from the patient's healthcare providers, where each document of the patient's medical records is categorized using the backend server; a database connected to the backend server for storing the categorized documents, where access to the categorized documents is controlled directly or indirectly by the patient or his legal representative; and a Web server connected to the backend server and to a client system, where the Web server processes a search request initiated by the client system for a select set of one or more document(s) out of all the stored categorized documents.

[0022] A further aspect of the present invention includes a method in a computer system for displaying a document log of the medical records of a patient. A table is displayed that includes multiple rows, where each row includes multiple columns, and where a column includes one or more cells associated with a category. Document ID data, which identifies a document in the patient's medical records, is displayed in a cell of a row.

[0023] Another aspect of the present invention includes a method, using a computer, for commenting on a medical record by a patient. First, an electronic image of said medical record is searched for using a category assigned to the medical record. The electronic image is stored in a database, where access to the electronic image is controlled by said patient. Next, a patient's comments and/or a provider's comments are associated with the electronic image and stored in the database. When the electronic image is recalled the comment is also recalled and displayed concurrently with the electronic image.

[0024] Another aspect of the present invention includes a method in a computer system for displaying a document timeline of documents in a patient's medical records. A first axis is displayed having sequential calendar time units, and a second axis is displayed listing the documents organized by medical category. For a particular document, there is an indication on the first axis of a calendar time unit having the date of creation and the name of the author of the particular document.

[0025] Yet another aspect of the present invention includes a method in a computer system for displaying a progress note timeline of multiple progress notes in a patient's medical records. A first axis is displayed indicating sequential calendar time units, and a second axis is displayed indicating the total number of progress notes per calendar time unit.

[0026] An embodiment of the present invention includes a method for a doctor using a patient's medical records, including clinical pages, stored in a patient directed computer storage area. First, the doctor selects a category that's of relevance from the list of multiple categories that could be used to categorize each clinical page. Next, a subset of the clinical pages is retrieved from the computer storage area, where the subset includes those clinical pages belonging to the category and not designated private by the patient. An "Availability" factor is calculated as a ratio of the number of clinical pages in the subset to the total number of clinical pages categorized with that category. Lastly, the Availability factor is displayed on the title page under the category for use by the doctor in evaluating the completeness of the subset.

[0027] Another embodiment of the present invention includes a method for a doctor using a patient's medical records, including clinical pages from a healthcare provider, stored in a patient directed computer storage area. First, the doctor selects a category of the multiple categories classifying the clinical pages. Next, a subset of the clinical pages belonging to the category is retrieved from the computer storage area. A "Source" factor is calculated as the ratio of a number of clinical pages in the subset obtained directly from the healthcare provider (as opposed to indirectly from the patient) to the total number of clinical pages in the subset. The source factor is then displayed to the doctor for use in evaluating reliability of the subset.

[0028] These and other embodiments, features, aspects and advantages of the invention will become better understood with regard to the following description, appended claims and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] **FIG. 1** illustrates the fragmentation puzzle of a patient's medical records of the prior art;

[0030] FIG. 2 is a block diagram of an example flow of a patient's medical records among different healthcare providers of the prior art, that results in the fragmentation puzzle of FIG.

[0031] FIG. 3 is a block diagram illustrating the hub and spoke flow of a patient's medical records between different healthcare providers medical record systems and a patient's central data repository of one embodiment of the present invention;

[0032] FIG. 4 shows the results of a consolidation of medical records from the multiple healthcare providers of FIG. 1 into a patient directed central data repository;

[0033] FIG. 5 is a client-server architecture of one embodiment of the present invention;

[0034] FIG. 6 is a flowchart for the process of managing a patient's medical records according to an embodiment of the present invention;

[0035] FIG. 7 shows the preferred process of managing a patient's medical records of another embodiment of the present invention;

[0036] FIG. 8 is an example of a user interface for entering the request for medical records of multiple providers (historical and current) of a given patient;

[0037] FIG. 9 is an example of a user interface showing the collection status of a patient's medical records;

[0038] FIG. 10A is an example of a user interface for a system of categorizing a scanned page;

[0039] FIG. 10B is an example of a user interface for a system of cross-categorization, i.e., adding an additional category to an already categorized page or making edits to the categorization of a scanned page.

[0040] FIG. 11 shows an example of an electronic image with the categories added to the header and footer of the scanned page from FIG. 10A;

[0041] FIG. 12 is an example of a window of a physical exam summary page of a patient's medical records;

[0042] FIG. 13 shows an example of a comment box in which the patient can enter his own comments related to the physical exam summary page of FIG. 12;

[0043] FIG. 14 is an example of a document appended with patient's comments;

[0044] FIG. 15 is an example of a page listing the medical sub-categories representing various types of page (Page Type by Medical Category) found in a patient's medical record file and the order of presentation of particular tab sections for two reports that display record pages along these medical sub-categories of an embodiment of the present invention;

[0045] FIG. 16 is an example of a user interface allowing the designating of some of a patient's medical records as "Private";

[0046] FIG. 17 is an example of a document log sorted by medical sub-categories (page type), an aspect of the present invention;

[0047] FIG. 18 is an example of a document timeline for the documents in FIG. 17, an embodiment of the present invention;

[0048] FIG. 19 is an example of a timeline of the number of a doctor's progress note of an embodiment of the present invention;

[0049] FIGS. 20-1 to 20-7 show the database structure of an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0050] In the following description, numerous specific details are set forth to provide a more thorough description of the specific embodiments of the invention. It is apparent, however, to one skilled in the art, that the invention may be practiced without all the specific details given below. In other instances, well known features have not been described in detail so as not to obscure the invention.

[0051] FIG. 3 is a block diagram illustrating the hub and spoke flow of a patient's medical records between different healthcare providers medical record systems and the patient's central data depository of one embodiment of the present invention. The example of FIG. 3 uses the same healthcare providers as FIG. 2. The different healthcare provider medical records systems are shown in parentheses, as the records are actually transferred from one healthcare provider system to another healthcare provider system. The patient either has a central data repository himself that he directly controls or has a service provider (or another person or organization) having a central data repository for him, that the patient indirectly controls (i.e., the service provider must have the patient's explicit or implicit permission before any of the patient's medical records can be shown to a third party). Both of these central data repositories of a patient's medical records are called, herein, a patient directed central data depository 210 or "central data depository", as the patient or his legal representative has direct or indirect control on who has access to his medical information.

[0052] In the example of FIG. 3, a patient's childhood doctor is general practitioner 110, e.g., a pediatrician like in FIG. 2. However, unlike FIG. 2 the patient directed central data repository 210 does contain a complete copy of all of the patient's medical records authored by general practitioner 110. When patient 210 changes doctors to general practitioner 112, general practitioner 112 gets any of patient's past medical records, e.g., those kept by general practitioner 110, from the central data repository 210 rather than a past healthcare provider's medical record system. Copies of the patient's medical records generated by general practitioner 112 are also transferred to the central data repository 210. When the patient goes to specialist 114, specialist 114 uses the central data repository 210 for past medical records e.g., medical records kept by general practitioner 110 or current medical records, e.g., medical records kept by general practitioner 112. Similarly, when the patient changes health plans and gets a new general practitioner 120 and a new specialist 122, these doctors need only access the central data repository 210 to get any necessary medical records of the patient. Duplications and gaps in documentation are reduced by the current doctor being able to see a list of what's available in this central data repository 210. Thus the hub and spoke arrangement of FIG. 3 significantly

simplifies the information flow given in FIG. 2, and significantly reduces or eliminates the fragmentation of a patient's medical records across the different healthcare providers.

[0053] FIG. 4 shows the results of a consolidation of medical records from the multiple healthcare providers of FIG. 1 into a patient directed central data repository. Besides the major advantage of having a complete set of medical records available to the patient and his healthcare providers, duplicate records can be removed and the various pieces of a patient's medical history can be organized in a coherent and consistent fashion.

[0054] While the retrieval and consolidation of a patient's medical records into one central data repository is a necessary condition in using the patient's medical history effectively, such a collection is not sufficient. Unless the voluminous number of documents in a patient's medical records are adequately organized and presented, there is a small chance that a relevant subset of the collection of documents can be retrieved and displayed in a timely and relevant manner for use by a doctor currently diagnosing and treating the patient. Thus categorizing or classifying of each document in a patient's medical history is another necessary condition in using the patient's medical history effectively. One or more of the categories or classes is then used during the retrieval to order a part of or all of the collected documents, and a relevant subset for presentation is selected from the ordered documents based on a filtering criteria. For example, if a doctor's notes of the collection of documents are ordered chronologically by date of creation, then only the notes over the past year may be displayed.

[0055] The term "document", as used herein, comprises a text or word processing file, an image file (e.g., pdf, jpeg, bmp), a page of a paper-based or electronic medical record, a film (e.g. X-Ray), a video or audio clip, a multimedia file, or a page of any softcopy or hardcopy of information related to the patient. The term "medical" is not limited to the medical field, but includes dental, pharmaceutical, optometric, audiological, chiropractic, physical rehabilitation, mental health, insurance and contact information relating to the patient, and/or any other traditional or non-traditional healing fields. The term "clinical" refers to any medical information (historical or current), provider or test-result based or information provided by the patient, that can be used as data for proper diagnosis and treatment of the patient.

[0056] FIG. 5 is a client-server architecture of one embodiment of the present invention. Web server 348 of server system 310 is connected via a communications network, e.g. the Internet 312, to client systems 320, 322, and 324. The server system 310 includes a backend server 340 connected to a scanner 342, a printer/fax 352 and a database 344, where database 344 stores electronic copies of the patient's medical records. The backend server 340 is connected to Web server 348. A client system 320 includes a personal computer (PC) 330 and a telephone 332, and printer (not shown). The PC 330 is connected to the Web server 348 via Internet 312. The telephone 332 is connected to a phone system interface 350 via public telephone system 314. Examples of the phone system interface 350 include a human interface, voice recognition unit (VRU), or automatic call system (e.g., for sending automated announcements to patients about keeping their records updated at specific time intervals.)

[0057] A patient's medical records, stored off-line in database 344, can be accessed by a client system, e.g., 320, through a scheduled "Session". A "session" is a time window in which the patient's medical information is available for access on Web server 348. The patient or the patient's authorized representative at, e.g., client system 320 uses telephone 332 to call phone system interface 350 to request a time window (e.g., start time and duration) to logon to Web server 348, and the patient receives a Session ID from the backend server 340. The Session ID instructs backend server 340 when, and for how long information is placed on-line for access. The client system 320 logs on to Web server 348 with the client's Login Name (or Member ID), password, and session ID at the given time. If the Session ID given by the client system 320 is the same as the session ID given by the backend server 340 to the patient via the phone system interface 350, then medical information on the patient, e.g., a portion or all of a patient's medical records, stored off-line in database 344 is transferred to a temporary storage location on Web server 348 by the backend server 340. If the session ID is incorrect or the patient logs on outside of the given time window, then no medical information on the patient is transferred to the Web server 348. When the patient logs off either explicitly or implicitly, e.g., by not entering information for a predetermined length of time or by exceeding the time window, the medical information on the patient is deleted from the temporary storage area on the Web server 348. 16

[0058] In one embodiment the phone system interface 350 is a call center whose operators use Web pages from the backend server to schedule a session for the patient. In another embodiment the phone system interface 350 is a phone server connected by a local network to the backend server 340, where only the requested time window and session ID for the patient is passed between the phone server and the backend server 340.

[0059] Record distribution can be done directly by a patient sending an email or fax from his client PC 330 or indirectly by calling a service entity by using the telephone system (332, 314, 350), which then retrieves relevant documents from backend server 340 for distribution via email, fax 352, CD-ROM (not shown), or hardcopy generated by printer 352 and then shipped off via traditional mail

[0060] FIG. 6 is a flowchart for the process of managing a patient's medical records according to an embodiment the present invention. At step 410 the documents from a patient's medical records are collected from the patient's current and past healthcare providers. The documents may be collected in various forms to include electronic, paper-based, or film. For the documents that are paper-based, they are converted to electronic images by scanner 342. Each document in the patient's medical record is categorized (or classified) according to a predetermined categorization (or classification) system (step 412). In one embodiment all documents are converted into electronic format, except the medical images on film which are labeled with their categories, but not converted into electronic format. In an alternative embodiment, these medical images are also converted into electronic format. At step 414, the categorized elec-

tronic documents are stored in database 344. Upon request of a client system 320 to Web server 348 (with the appropriate session ID), backend server 340 retrieves and arranges some or all of the documents, using one or more of the categories, or retrieves information about the requested documents, e.g. number of documents in a given time period, from database 344 (step 416). The arranging of the documents, includes a sorting process using one or more of the categories, e.g., date of creation, and a predetermined sorting criteria, e.g., reverse chronological order. Next a filtering process is performed based on a predetermined filtering criterion, e.g., all of the sorted documents in the past year or all of the documents describing or listing medications. In another embodiment the filtering is done concurrently with the sorting. In yet another embodiment the filtering is done before the sorting. At step 418 the filtered arranged documents or information about the requested documents are sent via Web server 348 to be displayed on PC 330 at client system 320. The filtered arranged documents may also be emailed, faxed, stored in CD-ROM or printed and mailed on behalf of the patient (or for certain medical images retrieved from a film archive), either by page, section, or by the entire report, e.g., Combined Medical Records (CMR) report or Medical Summary (MS) report or the patient may print them for his own use using a printer (not shown) attached to a client system 330 (step 419).

[0061] FIG. 7 shows the preferred process of managing a patient's medical records of another embodiment of the present invention. The process is a cyclical process which receives a patient's medical records from a plurality of healthcare providers, e.g., 422-1 to 422-8 (both individuals 422-1 to 422-4 and organizations 422-5 to 422-8). The process then produces an output of either all or a portion of a Combined Medical Record report 424 or a Medical Summary report 426 or both that is an organized version of some or all of a patient's medical records. This output is then made available to the patient and to one or more of the plurality of healthcare providers, as authorized by the patient. The patient 428 is the center of this process and has the final say or control over which healthcare providers to request a copy of the patient's records, and therefore whose provider records are to be stored, and whom to authorize access for viewing and/or obtaining a copy. The process is performed preferably by a service provider, who acts on behalf of and with the permission of the patient 428. The process has a number of sub-processes: collection of initial records and of updates to these records 430, storage 432, organization 434, presentation 436 and online access and other forms of distribution 438.

[0062] At collection sub-process 430, a patient's initial medical records and any subsequent updates to these records are collected. The initial collection effort of a patient's medical records from the multiple healthcare providers consolidates a patient's medical data in one place, i.e., the patient directed central data repository, so that the patient's medical data can be reviewed on a comprehensive and as importantly, consolidated basis. A search engine using predetermined databases locates the whereabouts of a patient's past healthcare providers based on minimal information about provider's last name, city, and state. The healthcare provider is contacted in order to verify contact information, request record copies, and check record collection logistics. The patient is provided with periodic updates on the status of collecting his records. Each step of the collection process is automatically tracked.

[0063] Updates to the patient's initial medical records are collected to keep a patient's medical records current. Periodic "postcard reminders" or "email reminders" are set-up to remind the patient and his record providers to send in any new pages added to the patient's record since the previous collection. Using a database, the patient and record-provider are informed of the most recent type and date of documents collected. "Authorization stickers" to be pasted on lab tests or exam requests are mailed so that the tests and requests can be sent in for updating a patient's records.

[0064] At storage sub-process 432, the patient's medical records, including paper-based records along with a section for Patient Inputs, are stored electronically in a patient directed central data repository, e.g., database 344. A patient's medical records are stored permanently (or for as long as the patient wants) so that they are available for use in the future by the patient, his healthcare providers, his family members, and current and future offspring (legacy). The paper medical records are scanned into the computer, e.g., scanner 342 coupled to Backend server 340, enhanced, and orientated to give an upright presentation. Each scanned page is tagged with the patient's name, healthcare provider name, and file ID. In addition the patient inputs his medical information in order to give his perspective on his health and to offer one place for his healthcare providers to view all relevant patient-provided information. In an alternative embodiment, either the healthcare provider or a third party scanning service has previously converted the paper medical records into electronic images. As discussed before, each electronic image is tagged with the patient's name, record-provider name, file ID, and other useful categories.

[0065] At organization sub-process 434, the patient's medical records are organized across the multiple healthcare providers by pre-defined schema. This organization enables providers and patients to easily find and sort through pages of a patient's medical records. The categorization system is such that the same categories are used across the multiple healthcare providers. Hence, a standard set of categories are used for the documents from the multiple healthcare providers. The pages can be sorted by, section/categories, reverse chronological order, numerically by Document ID, alphabetically by name of the record-provider, name of the author or name of the medical specialization pertaining to the author. Every page is examined and assigned one or more categories of "page type." There are 30+categories for describing the page type (or "medical category") of a particular page in a medical record file. These range from typical and commonly used (such as "Labs & Cultures", "EKGs", "Progress Notes"), to more detailed (multiple categories for Imaging, multiple categories for Hospital Notes, multiple categories for Labs & Cultures), then to even more refined classifications for narrowing the scope of the page search (such as difference between typed and un-typed notes; difference between "Inpatient" or "Outpatient" visits for doctor's or consultative notes.). In addition to these medical sub-categories ("Page Type"), there are several other indices used to categorize a page including: Patient Name, Member ID, Document ID, Author Name, Author Date, Author Specialization (to the extent that the author is a doctor), and Record-Provider Name.

[0066] At the presentation sub-process 436, some or all of a patient's medical record information is presented in reports. The presentation of the patient's medical information is consistent across the multiple providers in order to enable ease of use and understanding. The two main reports, i.e., the Combined Medical Records (CMR) and the Medical Summary (MS) reports, include most or all of the following presentation features: patient comment boxes, patient input forms, selected clinical pages (for the Medical Summary), patient-added pages (additional record pages to be extracted from patient's CMR and inserted into MS report for presentation), record indicators (availability factor and source factor calculated by algorithmic rules), document logs (by date, page type, and specialization), and visual time lines (timeline of documents and timeline of progress notes).

[0067] At access/distribution sub-process 438, on-line access by patient himself or by patient-authorized third party to a patient's medical records via an Internet browser is also provided. Online access enables access and availability of a patient's medical records when they are needed, and anywhere where there is Internet connection. For standard (non-emergency) access, the security and access protocols are based on an approach from a risk management standpoint, which limits the amount and length of time a patient's data can be accessed via the Internet. The access protocol limits exposure of data to unauthorized access by controlling the amount of data made available and when the data is accessible via the Internet. For emergency access, the scope of content in the patient's medical records is limited for unknown (undesignated) 3rd party healthcare providers.

[0068] Further at access/distribution sub-process 438, a patient distributes some or all of his medical records to third parties where needed. Distribution requires a patient's authorization on a "Send To" form before distribution can begin. The Medical Summary and/or Combined Medical Records report can be distributed in several formats, including: individual pages, sections, or the entire report copy. Patients can make distribution requests from their personal pages on the web server or by telephone, fax, email, or mail. Distribution can be made by, but is not restricted to, fax, email, CD-ROM, paper copy, or a bound copy.

[0069] Examining FIG. 7 in more detail, collection sub-process 430 requires the identity and address of the healthcare provider, before a patient's medical records can be collected from that healthcare provider. Once the identity and address of the healthcare provider is known, server system 310 automatically generates a letter for the patient's signature to request a copy of the patient's medical records from the physician or health-care provider organization.

[0070] FIG. 8 is an example of a user interface for a healthcare provider search engine of an embodiment of the present invention. In the preferred embodiment, this search engine is used by the service provider in the collection sub-process to locate the patient's healthcare provider. In an alternative embodiment, the search engine is a stand-alone that can be used to locate any healthcare provider. The user interface 512 executes on a Web browser 510, that is displayed on client system PC 330. The user interface 512 allows the patient to fill in partial information about a current or past healthcare provider, for example, the patient could provide some minimum information such as a doctor's last name (or organization name), city, state, and specialty, and the search engine, executing on Web server 348, searches several databases to locate the rest of the doctor's (or organization's) location information. User interface 512 includes a selection 520 to choose the type of healthcare provider, e.g., a doctor, an input area 522 to enter the name of the physician or health-care organization, e.g., Jane Doe, M.D., and a selection 524 to choose the specialization of the physician or organization. User interface 512 further includes several address input areas, 526, 527, 528, 530, and 532 to enter the current address of the doctor or health-care organization. Typically, the required address entries are for the city 528, e.g., Any City, and state 530, e.g., CA, or alternately, the zip code 532, e.g., 92930. User interface 512 further includes entry areas for the office phone 534 and for the approximate date of the first appointment 536. There is a selection button 538, that when selected, automatically searches a plurality of predetermined databases to fill in the rest of the location information, e.g., address 526 and 527 of the physician or organization. Table 1 below gives examples of web sites that the search engine searches to find the missing location information. In an alternative embodiment the search of the Website in Table 1 is done manually. In another embodiment the research for locating the provider is done using non-Web resources.

TABLE 1

http://www.docboard.org/
http://www.ama-assn.org/aps/amahg.htm
http://www.chiropractor-directory.com/
http://www.theinternetdirectorier.com/chirohealthcaredirectory/
http://www.sermed.com/hospital.htm
http://www.medicalhospital.com/index.html
http://www.hospitalselect.com/cnrb__dhjwww/hp__hospselect.main
http://neuro-www2.mgh.harvard.edu/hospitalwebusa.html
http://www.thephysicandirectory.com/
http://www.thedentistdirectory.com/

[0071] After contact information in FIG. 8 is either filled in by the user or by the search system, a request for the patient's medical records from the Physician/Organization 522 is created. Next, a Collection Request ID is assigned to the request along with inputs for specific record fields identified by the Collection Request ID, the Member's (i.e., patient's) ID, the information from FIG. 8, the date of the request and the status of the request is inserted into the CollectRecords table of the database 344.

[0072] The collection process can be in one of the several states, including: 1. Record collection request received, waiting for authorization form from member (i.e., patient); 2. Authorization form received records requested from provider; 3. Records not received from provider, second request sent; 4. No response to second record request, third request sent; 5. No response to third record request, review options with member; 6. Records received, waiting to be processed; and 7. Records processed into database. The current collection status is updated by personnel of the central data repository service via a window similar to window 510, but with an extra pull-down menu that allows one of the above seven status states to be selected or updated.

[0073] FIG. 9 is an example of a user interface showing the collection status of a patient's medical records. The display 550 includes the window 552 (Member Administration) that has the record status. In column 554 is the collection request ID for each request. In column 556 is the

name of the organization or physician to whom the record request is sent, for example, "Cameron Medical Center" in box 570. Also the "Edit" link in box 570 brings up a window for "Cameron Medical Center" similar to FIG. 8, and allows the information in FIG. 8 to be changed. Column 558 displays whether or not the search engine was used to fill in missing contact information in FIG. 8. Col. 560 gives the date the record collection began. Column 562 gives which of the seven states, listed above, the present collection status is in. Column 564 has comments related to collection of the medical record.

[0074] Once the patient's medical records are received, every document is examined and categorized (organization sub-process 434). For paper based medical records, each page is scanned via scanner 342 into an electronic image, stored in TIFF format, and then converted into PDF format, once categorization is done. Each electronic image is examined and categorized. Among the categories assigned is a page category that has a plurality of medical sub-categories. These medical sub-categories include, for example, documents on typical medical results and notes, such as a "Labs & Cultures" sub-category, a "Consultations" sub-category, a "EKGs" sub-category, and a doctor's "Progress Notes" sub-category. Some pages could have multiple medical sub-categories (cross-referenced). The "Immunizations" sub-category, for example, has documents that are also found in the "Progress Notes" sub-category and in "Physical Exams" sub-category. In an alternative embodiment, some or all of the paper-based records have been previously scanned at the healthcare provider and these scanned image files are examined and categorized, i.e., no scanning is needed by the server system 310.

[0075] FIG. 10A is an example of a user interface for categorizing a scanned page of an embodiment of the present invention. The scanned page shown in window 714 is of a medication summary of patient Mary Jane Adams. Window 712 is used to assign categories to the scanned page in window 714. Window 712 includes an entry area 720 for the author of the scanned page, a menu 722 to select the specialty of the author given in entry area 720, menus 724 to enter the date the author generated the paper-based page, and a menu 726 to give the page type, i.e., medical sub-category as listed in FIG. 15, and cross-indexed (given an alternative page type), where it makes sense.

[0076] When the information in FIG. 10A is submitted to the Backend server 340, a Document ID is assigned to the scanned page and the Document ID, the information from FIG. 9, the Collection Request ID, the Member's ID, the Record-Provider's Name, and the date the record was entered is inserted as a record into the DocumentLog table of the database 344. The scanned page is formatted into a PDF format file with a header and a footer having labels of one or more categories. The formatted file is stored as an electronic image file (for example FIG. 11) with the Document ID as the filename and a .pdf extension.

[0077] FIG. 10B is an example of a user interface for a system of cross-indexing, i.e., adding an additional category to an already categorized page or making edits to the categorization of a scanned page. Selection 734 allows other medical sub-categories as given in FIG. 15 to be added as classifying categories for the page 714, i.e., cross-indexing. These additional medical sub-categories can be used to search and sort the page 714. There is also the choice 736 to make edits to the author 740, date 742, or specialization 744 of an already categorized page 714. Also selection 738 allows deleting a page that has been duplicated for cross-indexing purposes.

[0078] FIG. 11 shows an example of an electronic image 810 with the categories added to the header 814 and footer 816 of scanned page 714 of FIG. 10A. The categories shown in this example in the header 814, include: the document identifier, "Document ID: 455"820, the page type (medical subcategory), "Medication and Allergies"822, the patient's name, "Mary Jane Adams"824, and the patient's member identifier, "MemberID 532"826. In the footer 816 the categories shown include: the author of this page, "Author: Jane Doe, M.D."830, the doctor's specialization, "Specialization: Internal Medicine/Family Practice/Primary Care"832, the date the author created the document, "Author Date: May 18, 2000"834, and the name and number of the service provider, "Peoplechart (415)-362-8800". In addition any hardcopy of any electronic image is also labeled with these descriptive fields in the header and footer. Hence pages can be easily traced back to a particular file or section, date, or record provider name, and re-ordered when they become disorganized.

[0079] In one embodiment the categories for the header that appear on each page include: Document ID, Patient Name, Page type(s), and Patient's Member ID. And the categories for the footer of each page include Author of the page, Specialization of the Author, if relevant, Date in which page content was created, and optionally, the service provider's phone number. A category that does not but could appear on the example page is the name of the record-provider who provided the records. In most cases, this can be an important organizational tool for those patients who see multiple healthcare providers and want to find the pages that belong to a particular healthcare provider. In other embodiments some of the information in the header may be absent or in the footer and some of information in the footer may be absent or in the header. In an alternative embodiment, other categories may be added to the header or footer, such as patient aliases, maiden name, patient's date of birth, healthcare provider, or additional categories apparent to one with ordinary skill in the arts.

[0080] A patient and/or the patient's doctor(s) can add comments to the electronic copy of their medical records by launching a comments dialog box. The comments then become an integral part of the medical record, i.e., the comments are electronically linked to the medical record. This provides the patient with a valuable tool to update, correct and add to the informational contents of the medical record. FIG. 12 is an example of a window 720 of a physical exam page 722 of a patient's medical records. The comments link 721 in FIG. 12 is used to launch the comments dialog box. FIG. 13 shows an example of a comment box 724 in which the patient can enter his own comments related to the physical exam summary page 722 of FIG. 12. In this example the patient types "the comments entered here will be appended to this clinical page". When the "Add/Update Comment" button 726 is clicked the comment is appended (or linked) to the medication summary page 722.

[0081] FIG. 14 is an example of a record page document with a patient's comments appended to it. Page 732 is the

physical exam page 722 of FIG. 12. The comment page 734, which is attached or linked to the physical exam page 722, has the comments typed in comment box 724 of FIG. 13.

[0082] FIG. 15 lists the medical sub-categories describing page type category of an embodiment of the present invention. In this example there are 35 medical sub-categories associated with the page type category as shown by "Index ID", column 912. The table 910 in FIG. 15 includes a column 920 having a description of each medical sub-category, and a column 922 for the code used for each sub-category. Also included in table 910 is a column 914 showing the sub-sections in the "Clinical Pages" section of the Combined Medical Records (CMR) report; a column 916 showing the section numbers for the document timeline graph; and a column 918 showing the sub-section numbers of the "Selected Clinical Pages" section for the Medical Summary (MS) report.

[0083] Some of the medical sub-categories in FIG. 15 have been broken down from a more general sub-category in order to help a doctor find information quickly, including 6 sub-categories for Imaging, 5 different sub-categories of Hospital Notes, and 3 different sub-categories of Labs & Cultures. There are also sub-categories for helping patients and doctors to quickly select or differentiate the pages they want within those categories, such as Typed versus Untyped (handwritten). There are also 5 categories of "Other" to address and separate duplicate pages, irrelevant pages such as those concerning a different patient, title pages from healthcare provider files, and administration type pages. Thus all documents of a patient's medical history are categorized with at least one medical sub-category given in FIG. 15. The categories given in FIG. 15 are not to be interpreted as limiting, but are a preferred embodiment of the present invention. Other embodiments may have different categories or the same or a different number of categories. For example, The "Medications and Allergies" sub-category could be further divided into traditional and non-traditional medications.

[0084] Once the categorized documents are stored in database 344, these categorized documents can be sorted and/or searched. Pages can be found in a selected category or sub-category by using "Search By" category fields displayed on a client system, e.g., client's personal computer 330. Moreover, pages can be re-categorized into different categories at the request of the patient. The categorized documents can also be sorted into a tabbed collection of documents and presented as a report, e.g., the Combined Medical Records (CMR) or Medical Summary (MS) report, as described with tab names displayed in the order of prioritization as shown on 914 and 918 (FIG. 15), respectively. These reports are either presented on the client system, e.g. 320, using a Web browser connected to Web server 348, emailed as an attachment, faxed, saved on a CD-ROM or printed, or both.

[0085] The Combined Medical Records report is an organized and comprehensive portfolio of a patient's medical history. The CMR includes both clinical record pages collected and compiled from a patient's current and past healthcare providers and a section called Patient Inputs, which provides an opportunity for patients to add their perspective and assessment of their health history, condition, and objectives. The CMR further includes organizational tools such as document logs, providing a page-by-page inventory of the medical records in the patient's files and a time line of activities represented by documents collected over the course of a patient's health history. An example of a CMR outline by section and sub-section is given in Table 2 below.

TABLE 2

SECTION	SUB-SECTION
A. Table of Contents	
B. Patient Inputs	
C. Document Logs	
	1. By Date
	2. By Medical Category
	3. By Specialty
D. Document Timeline	
E. Clinical Pages	
	1. Medications & Allergies
	2. Immunizations
	3. Patient Intake
	4. Physical Exams
	5. Progress Notes
	6. Consultations
	7. Operative Notes
	8. ER Reports
	9. Hospital Summaries
	10. EKGs
	11. Imaging Reports
	12. Special Tests
	13. Labs & Cultures
	14. Therapy Notes
	15. Billing & Insurance
	16. Other

[0086] A patient may designate any document in his medical records as "Private". These "Private" documents are only viewable by the patient and are not included in the CMR or MS reports. If the patient wants to provide "Private" documents to another party, this can be done on a per document basis.

[0087] FIG. 16 is an example of a user interface 930 allowing the designating of some of a patient's medical records as "Private". FIG. 16 has information in its columns similar to FIG. 17, except there is a "Private" column 932, that allows a patient to select which documents in column 954 are to be designated "Private". After the patient checks the checkboxes, e.g., checkbox 934, of the private documents, he clicks the button "Hide Private"936 to complete the hiding process, i.e., only the patient can view the private documents. Hiding Document 455 (checkbox 934) means that the information relating to Document 455 will not appear in the document logs, timelines, or reports as illustrated in FIG. 17 and FIG. 18.

[0088] Both the CMR and MS reports have record indicators to inform the doctor whether some of the patient's medical records are missing from the report, i.e., marked "Private" in the database. Another record indicator that informs the doctor whether the clinical pages were provided by another healthcare provider or by the patient. These indicators assist the doctors in determining the reliability of the medical records.

[0089] "Availability" factors are calculated and displayed for each sub-section of the clinical page section of the CMR and for the whole report. These factors are also applicable to each sub-section of the selected clinical pages of the MS. The availability factor is the ratio of the number of pages

presented in the report to the total number of pages collected, by section and by entire report. This indicates to the physician whether some pages have been classified as Private and are not available for viewing. For example, an availability factor of 75% on a subsection of four documents means for example, that 3 out of the 4 documents in the subsection are included in the sub-section, while one document has been excluded from the presentation or marked as "Private."

[0090] "Source" factors help measure the classification of the source, individual or organization who sent in the records, for each sub-section of the clinical pages in the CMR and for the whole report, i.e., those records provided or sent in by a patient versus those records sent in or provided by provider. Since many physicians are concerned that they have a complete set of records, they assess the credibility of these records by the source-sender of the records, i.e., whether the records have been obtained directly from a healthcare provider or indirectly from the patient. This information is provided as a ratio of the number of clinical pages in a medical sub-category obtained directly from healthcare providers to the total number of pages in this medical sub-category. A source factor of 90% in a subcategory having ten pages would indicate that nine pages came directly to the data repository service from the healthcare provider, and one page came from the patient.

[0091] After the "Table of Contents" section, the next section in the CMR is the "Patient Input" section. The patient input section allows a patient to share his perspective of his health with his doctor. This section includes: a patient's assessment of his health history, current health condition, and objectives; clinical information that the patient himself fills in order to supplement his medical records, such as medications, immunizations, and allergic reactions; and personal and medical contact information, health insurance, and administrative information. The patient input section includes two major parts completed by the patient. Part I provides the patient's personal and medical information, description of health statistics, family history, and assessment of his health conditions. Part II provides medical and personal contacts for times of medical emergencies and other relevant administrative information.

[0092] The Part I, Health Assessment, is further divided into: personal information, current health concerns, health history, allergies & reactions, medications, doctors be aware, general health & background (including immunizations), hospitalization history, family health history, alternative/complementary medicine, and health objectives & experience. Part II, Personal Contacts and Administrative Information, is further divided into: doctor contact information, emergency contact information, employment information, and health insurance.

[0093] The third section in the CMR is the "Document Logs" section. Document logs provide an inventory listing of every page contained in a patient's collected medical records. This list can help the patient and her doctor spot a specific clinical page or review the amount, type, and timing of clinical documents available in the patient's files. Pages may be sorted by sub-categories, for example: 1) Document ID#, 2) Document date, 3) Record-provider name, 4) Page type by medical sub-category, 5) Author of the document and 6) specialization of the author. In one embodiment, the CMR documents are sorted by the document date, by medical subcategory, and by doctor specialization to produce three different logs.

[0094] A document log sorted by date, provides an inventory of pages in a patient's compiled records, presented in reversed chronological order based on the date shown for creation of the page content. When a document cannot be dated based on information from the page, a default date is chosen that places the document at the end of the log. With default dates, the patient is advised to review and provide a date if known or available. When a document has multiple dates listed on the page, such as pages found in Progress Notes or Medication Refill Logs, the most recent date is chosen. However, due to the fact that there are usually multiple dates for Progress Notes, pages of this type are shown separately in its own Timeline table.

[0095] A Document log sorted by medical category provides an inventory of pages in a patient's compiled records, organized by sections made up of commonly used medical sub-categories such as medications & allergies; hospital summaries; labs & cultures; etc. (see FIG. 15). Within each sub-category, pages are sorted in reversed chronological order. When a document cannot be placed in a specific medical sub-category, it is placed in a sub-category labeled "Other: Unclassified" and placed at the end of the log.

[0096] A document log sorted by specialization organizes the pages based on the specialty of the doctor or provider who wrote or created each page. This log provides an inventory of pages in a patient's compiled records, organized by name of the specialty of the physician(s) who authored the pages. The ability to sort charts by specialty helps patients bring information that is most relevant to their doctors, especially when they see a specialist about a particular condition. Pages authored by a location or an organization (such as a health clinic or laboratory) can be difficult to classify into specialties and are left for the patients or their doctors to categorize by relevant specialty. A document which cannot be categorized by specialty of author is included in a category labeled, "Unknown Specialty" and placed at the end of the log.

[0097] While the CMR provides three logs, other document logs based on the other categories can be generated and displayed. FIG. 17 is an example of a document log sorted by medical sub-category of an embodiment of the present invention. The window 952 includes the document log sorted by the medical sub-categories of FIG. 15. Column 954 gives the document ID for each document. Cell 970 has document ID 456, which is a link to the document image, e.g., the scanned image of the page (while document ID 455 (as selected by checkbox 934) is hidden from view as a result of having clicked on "Hide Private" button as described on FIG. 16). When "456" is selected a separate window (not shown) opens with the document's image. The four cells 972 have document IDs 457, 458, 459, and 460, which all have the same date 974, i.e., "Jun. 15, 1999" and the same page type "Physical Exams"978. The window 952 further includes, column 956 which has the date the document was created, column 958 has the healthcare provider that provided the document, column 960, "Page Category" and the primary "Sort Key" in this example, has the medical sub-category from FIG. 15, column 962 has the name of the doctor who created the document, and column 964 has the specialization of the doctor in column 962.

[0098] The fourth section in the CMR is the "Document Timeline" section. A timeline shows the pattern of events in the course of a patient's medical history by tracking the number of documents collected over time by sections made up of commonly used medical sub-categories (see **FIG. 15**) such as medications & allergies; physical exams, hospital summaries; labs & cultures; EKGs; imaging reports; and consultations with doctors, etc. Within each medical sub-category of the timeline, each mark on the timeline is identified by its unique combination of creation date and creator name (author). For each sub-category, each individual mark on the timeline can represent one or more pages that have the same date and author. Said another way, document that is made up of multiple pages (such as lab results) share only one mark on the timeline. The patient and doctor can visually gauge the type and frequency of activities performed by reviewing the number of "X's" that document(s) collected over the course of the patient's medical history by medical sub-category. Both patient's and doctor's comments about the timeline are provided at the end of section.

[0099] **FIG. 18** is an example of a document timeline for **FIG. 17** of an embodiment of the present invention. Window **1012** includes a column **1020** having the Document ID, column **1022** having the author of the document, column **1024** having the date the document was created, and a time line divided by months, e.g., the 12 months for year 2000 **1026** and the 12 months for year 1999. In addition, the window **1012** shows several sections, e.g., a "Medication & Allergies" section **1040**, that includes document ID 456 in cell **1030** (while document ID **455** (as selected by checkbox **934**) is hidden from view as a result of having clicked the "Hide Private" button **936** as described in **FIG. 16**), and a "Physical Exams" section **1040**, that includes document IDs **460, 457, 458, 459** in cell **1032**, since they all have the same date "Jun. 15, 1999"**1034** and same author "Jane Doe, M.D."**1035**, these documents get one mark only, **1038**. For document ID **456** (cell **1030**), there is mark **1036** on the timeline. For document IDs **460, 457, 458, 459** (cell **1032**) there is mark **1038** on the timeline. **FIG. 19** is an example of a timeline of the number of a doctor's progress note of an embodiment of the present invention. The timeline **1110** has the number of progress notes on the y-axis **1112** and the time, e.g., month, on thex-axis **1114**. For example, in June **1116** there were two progress notes written **1118**. The timeline **1110** is segmented by years, **1120, 1122, 1124, 1126,** and **1128**. A table **1130** lists actual dates in the month the progress notes were written. Table **1130** is also segmented by year **1132, 1134, 1136, 1138,** and **1140** to correspond to years **1120, 1122, 1124, 1126,** and **1128** of timeline **1110**, respectively. The progress notes may be color coded to represent the different providers who authored the notes.

[0100] The fifth section in the CMR is the "Clinical Pages" section. Medical record documents collected from a patient's past and present doctors are arranged into commonly used medical sub-categories (**FIG. 15**), and sorted by date in reverse chronological order. The sub-sections of the CMR for the "Clinical Pages" section are listed in Table 2 above.

[0101] Sub-section 1. The Medications & Allergies sub-section of the "Clinical Pages" section includes refill logs, medication notes, any pages in progress notes section referencing medications, and any pages in physical exams section referencing medications. This sub-section can be cross-referenced to the patient input sub-sections for allergies and reactions and medications. In one embodiment the cross-reference is done manually by the patient's doctor or medical records technician. In an alternative embodiment, there is a "cross-referenced" button on the display window so that a page can appear in multiple sub-sections of the CMR and Medical Summary Report. The cross referencing is done by the service provider. In an alternative embodiment the cross referencing may be done by the patient and/or healthcare provider.

[0102] Sub-section 2. The Immunizations sub-section includes documentation of immunization given to the patient. Pages may be cross-referenced to the progress notes, physical exams sub-sections, and to the general health & background of the patient input section.

[0103] Sub-section 3. The Patient Intake Applications sub-section includes an application usually filled out by patient during a first visit with a doctor.

[0104] Sub-section 4. The Physical Exams sub-section includes notes (typed or handwritten) related to patient during a physical examination.

[0105] Sub-section 5. The Progress Notes sub-section includes notes from a first visit and any subsequent outpatient visits with the patient's doctors.

[0106] Sub-section 6. The Consultations sub-section includes physician consultation notes from any outpatient setting.

[0107] Sub-section 7. The Operative Notes sub-section includes notes related to both inpatient and outpatient procedures, surgeries, and operations, performed in clinics or hospitals.

[0108] Sub-section 8. The ER Reports sub-section includes notes from visits to emergency rooms of hospitals or clinics.

[0109] Sub-section 9. The Hospital Summaries sub-section includes in-patient notes and consultations taken during patient's hospitalization, such as Admitting History & Physical, Discharge Summary, Consultations (Inpatient), Progress Notes (Inpatient), and any other hospital notes. Surgical, operative and procedure reports and notes, which are found in Operative Notes sub-section are excluded. Also any outpatient visits to clinics or hospitals, which are found in Consultations, Progress Notes, or Physical Exams sub-sections are excluded. Lab results and EKG's done in hospitals are excluded and found in the EKG and Labs & Cultures sub-section. In an alternative embodiment, the above excluded information is cross-referenced to the appropriate sub-sections.

[0110] Sub-section 10. The EKGs sub-section includes Electrocardiogram, ECG, or rhythm strips.

[0111] Sub-section 11. The Imaging Reports sub-section includes scans and ultrasounds including the following imaging results: X-Rays, Ultrasounds, Mammograms, CAT or CT scans, MRI scans, Nuclear medicine scans, DEXA (bone density) scans, PET scans and any other imaging test results.

[0112] Sub-section 12. The Special Tests sub-section includes any tests that are non-EKG and non-imaging

related, such as: ECHO-Cardiograms, Cardiac stress tests, Treadmill tests, Pulmonary Function tests, Dobutamine or Persantine stress tests, MUGAs, and any other specialized test results.

[0113] Sub-section 13. The Labs & Cultures sub-section includes: Blood chemistries, complete blood counts, prothmes and other tests of coagulation, arterial blood gases, urinalysis and urine chemistries, lipids, serologic tests, HIV tests (provided with patient's authorization), culture & sensitivities (including urine, sputum, blood, etc.), pathology reports, and any other lab or culture results.

[0114] Sub-section 14. The Therapy Notes sub-section includes any kind of log or notes pertaining to any kind of ongoing or periodic therapy or treatment, such as physical therapy, occupational therapy, radiation therapy, chemotherapy, any other therapy notes.

[0115] Sub-section 15. The Billing & Insurance sub-section includes copies of insurance cards and other information related to billing, insurance, and payment.

[0116] Sub-section 16. The Other sub-section includes record release forms, duplicate, irrelevant, misfiled, section, title, blank, and administrative pages that are not billing, insurance, or prescription related. Other administrative pages can include patient-sent or initiated letters, correspondences, forms, phone logs, record release forms.

[0117] The Medical Summary (MS) report enables both patient and doctor to quickly review a patient's medical condition and history both in medical emergency and in less urgent but time sensitive situations such as a first visit to a new doctor. It includes clinical record pages selected from a patient's combined medical record file. The section and sub-sections are given in Table 3 below.

TABLE 3

SECTION	SUB-SECTION
A. Table of Contents	
B. Patient Inputs	
C. Document Log	
	1. By Date
	2. By Type
	3. By Specialty
E. Select Clinical Pages	
	1. Medications & Allergies
	2. Immunizations
	3. Physical Exams
	4. Progress Notes
	5. Consultations
	6. Operative Notes
	7. ER Reports
	8. Hospital Summaries
	9. EKGs
	10. Imaging Reports
	11. Special Tests
	12. Labs & Cultures
	13. Therapy Notes
	14. Patient Added Pages

[0118] The first three sections, Table of Contents, Patient Inputs, and Document Log are the same as those in CMR. The "Select Clinical Pages" sub-section however has specific record pages from the CMR organized into sub-sections based on commonly used medical categories (the MS sub-sections are given in FIG. 15 column 918). For all sub-sections, pages included in each sub-section are automatically drawn from a patient's Combined Medical Records using a formula. The formula includes all documents with document creation dates within the N1 months prior to and including the patient's most recent date of activity for the specific sub-category or a minimum of M1 documents (regardless of time) each with an unique combination of creation date and creator name (author), which ever is greater. In one embodiment N1=12 and M1=3, but N1 and M1 can be any integer numbers. This formula is automatic and captures the most recent pages. However, other embodiments can use a different formula. For example the availability factor can be used to change the order of some documents with the most recent and most available being first.

[0119] In another embodiment, the first step in generating the group of selected clinical pages for each sub-section of the MS from the CMR is to retrieve from the DocumentLog table of the database the date of the most recent clinical page for the specified sub-section and target patient. In the second step, the number of Private clinical pages (clinical pages that the patient has designated to be viewable by the patient and no one else), the number of patient-provided clinical pages (clinical pages obtained directly from the patient rather than directly from a healthcare provider), and the total number of clinical pages with author (doctor/organization) creation dates within N2 months prior to and inclusive of the most recent clinical page obtained in the first step above, are obtained from the database. If the second step identifies less than M2 number of clinical pages, the next most recent clinical documents (i.e., over one year of the most recent clinical page) are added to the group so that there are at least M2 unique set of documents presented in the group. In an embodiment N2=12 and M2=3, but N2 and M2 can be any integer numbers. Next, the Availability and Source factors are calculated. The selected clinical pages in the presentation group are now retrieved from the database in reverse chronological order for the specified sub-section. This process is repeated for each sub-section of the "Select Clinical Pages" section.

[0120] The "Selected Clinical Pages" has sub-sections given in Table 3 above, and except for a new "Patient Added Pages" sub-section, is a subset of the sub-sections given for the "Clinical Pages" section of the CMR listed in Table 2 above.

[0121] The "Patient Added Pages" sub-section includes any clinical pages from the CMR that a patient would view as important to include in the Medical Summary. These pages are usually those pages that fall outside the range set by the automated formula for extracting selected record pages from the CMR.

[0122] In one embodiment of the present invention there are two flexible access plans for third parties having on-line access to a patient's medical records: emergency and non-emergency access.

[0123] In the case of a medical emergency, a healthcare provider can view the telephone number on the patient's membership card to call the phone server 350 (FIG. 5) with the patient's "Member ID". The amount of access given to the emergency healthcare provider has been pre-selected by the patient to be one of several possible Emergency Access levels. In one embodiment these could be Private (where no information is provided); Contact Information Only (where

only contact information for reaching the patient's doctor(s) and/or family members or next-of-kin are made available; Medication and Contacts Only (where medication descriptions and medication lists are added to contact information); and Full Access (where record pages from Combined Medical Records or Medical Summary are made available (except pages member classified as "Private").

[0124] Under non-emergency, i.e., normal situations, a patient selects what type of access to give to a third party, such as his doctor, in accessing his medical information. There may be various levels of access for a patient and potentially third-parties authorized by the patient. The access in one embodiment is set using a password protected Web page. The levels in one embodiment are given in Table 4 below.

TABLE 4

	Access Rights			
Access Levels	Assign (create) new users to access patient's account?	Schedule a specific time for viewing patient's medical records online?	Edit patient's records and distribute records to another party?	View patient's classified "Private" pages?
Patient	YES	YES	YES	YES
Surrogate	YES	YES	YES	NO
Provider	NO	YES	NO	NO
Limited	NO	NO (*)	NO	NO

(*) In one embodiment the patient must schedule a session for the third party.

[0125] The patient or his legal surrogate decides and authorizes the distribution of all or part of the patient's medical records to one or more third parties. A patient can transmit, via email or fax, a medical record or a group of medical records directly by using her web browser. Off-line distribution service is provided only with a patient's, legal surrogate or guardian's signed authorization on a "Send To" Authorization Form. There are several media which the whole or portion of a patient's CMR or MS report can be distributed by, to include: fax, email, CD-ROM, DVD, paper copy, or microfiche.

[0126] FIGS. **20-1** to **20-7** show the database structure **1410** of an embodiment of the present invention. The off-page connectors are given by the letters "a" through "w". The legend **1412** in FIG. **20-1** explains that "PK" is a primary key, "FK" is a foreign key, and "I" is indexed (i.e., an index structure is used to access records in a file). While in legend **1412**, "bold" text indicates a required attribute and "normal" text indicates an optional attribute in this embodiment, other embodiments have different combinations of required and optional attributes. An example of an entity set is "ClientDir" entity **1420** (i.e., the set of clients or patients) which has a primary key of "ClientIDX" (i.e., the client ID) **1422**, and several attributes, e.g., "LastName"**1424** (i.e., the client's last name). A particular value of "ClientIDX"**1422** can be used to determine the client's (i.e., patient's) physician, by using the foreign key "ClientIDX"**1442** in "Physician" entity set **1440** in FIG. **20-5**, to retrieve attribute "LastName"**1444** of the entity (i.e., a particular doctor) in the "Physician" entity set **1440** with the particular value of "ClientIDX" (i.e., the last name of the patient's doctor). The off page connector "p" from entity set **1440** terminates in ClientDir entity **1420** indicating the foreign key relationship. In addition, the particular value of "ClientIDX" can be used to search entity set "DocumentLog"**1450** (i.e., the set of document logs) to get the "DocumentIDX"**1454** (e.g., Document ID #) for each document associated with the client with the particular value of "ClientIDX" (i.e., the document IDs of the documents in a patient's medical records). The off page connector "t" from entity set **1450** terminates in ClientDir entity **1420** indicating the foreign key relationship.

[0127] While the embodiments given herein describe management of a patient's medical records, the scope of the present invention is not so limited but, includes other types of records where a person needs his/her records collected, categorized, stored (under his/her direction), and presented (e.g., displayed or distributed). Such other type of records include tax documents, wills, personal letters, legal papers, licensing/ownership papers, bills, payments, investments, and other personal information.

[0128] Although specific embodiments of the invention have been described, various modifications, alterations, alternative constructions, and equivalents are also encompassed within the scope of the invention. The described invention is not restricted to operation within certain specific data processing environments, but is free to operate within a plurality of data processing environments. Additionally, although the invention has been described using a particular series of transactions and steps, it should be apparent to those skilled in the art that the scope of the invention is not limited to the described series of transactions and steps.

[0129] Further, while the invention has been described using a particular combination of hardware and software, it should be recognized that other combinations of hardware and software are also within the scope of the invention. The invention may be implemented only in hardware or only in software or using combinations thereof.

[0130] The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense. It will, however, be evident that additions, subtractions, deletions, and other modifications and changes may be made thereunto without departing from the broader spirit and scope of the invention as set forth in the claims.

What is claimed is:

1. A method for managing a patient's medical records authored by a plurality of healthcare providers, wherein at least two healthcare providers of said plurality have different medical records systems, said method comprising:

categorizing a plurality of documents of said patient's medical records according to a categorization system;

storing in a central storage area said categorized plurality of documents, wherein access to said central storage area must be authorized by said patient; and

retrieving an ordered set of documents of said categorized plurality of documents, using at least one of a plurality of predetermined criteria.

2. The method of claim 1 wherein said central storage area comprises a database.

3. The method of claim 1 wherein said plurality of predetermined criteria include sorting said categorized plurality of documents in reverse chronological order of creation dates, by medical sub-category, by author, by author

specialization, in numerical order of document ID, by document provider, or any combinatioo thereof.

4. The method of claim 1 further comprising:

sorting said plurality of documents; aod

presenting said sorted plurality of documents based oo a selectioo criterion and a prioritization algorithm.

5. The method of claim 1 further comprising displaying said ordered set of documents to a current healthcare provider examining said patient.

6. The method of claim 5 wherein said displaying said ordered set of documeots to a current healthcare provider occurs only for documeots to said ordered set which are not marked private by said patient.

7. The method of claim 1 wherein said categorization system is the same for all healthcare providers of said plurality of healthcare providers.

8. The method of claim 1 wherein said categorization system comprises a plurality of categories, said categories comprising a document identifier.

9. The method of claim 8 wherein said categories further comprise: an author of a page, a specialization of said author, a date said page was created, a page type, a record source, or a name of a file provider.

10. The method of claim 1 wherein said plurality of documents comprises scanned paper-based pages of said patient's medical records.

11. A method for a patient accessiog said patient's medical records originating from a plurality of healthcare providers, wherein at least two healthcare providers of said plurality have different medical records systems, said method comprising:

collecting from said plurality of healthcare providers a plurality of documents of said patient's medical records, whereio said plurality of healthcare providers comprise a past and a presoot health care provider of said patient;

categorizing said plurality of documents according to a categorization system, having more than two categories;

storing in a storage area of a central computer storage said categorized plurality of documents, wherein said storage area is under control of said patieot; and

retrieving a documeot of said stored categorized plurality of documents according to at least one of a plurality of selectioo criteria, said plurality of selection criteria based oo said categorization system.

12. The method of claim 11 further comprising displaying said retrieved document to said patieot.

13. The method of claim 11 further comprising displaying said retrieved document to a third party after approval by said patient or said patieot's legal surrogate.

14. The method of claim 11 further comprising displaying said retrieved document to said patient, but not to said patient's legal surrogate.

15. The method of claim 11 further comprising distributing said retrieved documeot by fax, email, or hard copy.

16. The method of claim 15 wherein said hard copy comprises a floppy disk, CD, microfiche, or paper copy.

17. The method of claim 11 wherein said ooe selection criterion selects documeots of said stored categorized plurality of documents with document dates within the previous N months starting with said patieot's most recent date of activity or a minimum of M documents, whichever results in more documeots.

18. The method of claim 17 wherein N=12 and M=3.

19. The method of claim 11 wherein said categorization system is the same for all healthcare providers of said plurality of healthcare providers.

20. The method of claim 11 further comprising displaying a document log of said categorized plurality of documents to said patient.

21. The method of claim 20 wherein said document log is organized by document date, page type, or doctor specialty.

22. The method of claim 11 wherein said selection criteria selects documents in a category selected from a group of categories consisting of: Medications & Allergies, Immunizations, Patient Intake Apps, Physical Exams, Progress Notes, Consultatioos, Operative Notes, ER Reports, Hospital Summaries, EKGs, Imaging Reports, Special Tests, Labs & Cultures, Therapy Notes, Billing & Insurance, and Other.

23. The method of claim 11 whereio said selection criteria selects documents in a category selected from a group of categories consisting of: Medications & Allergies, Immunizations, Physical Exams, Progress Notes, Consultations, Operative Notes, ER Reports, Hospital Summaries, EKGs, Imaging Reports, Special Tests, Labs & Cultures, Therapy Notes, and Patient Added Pages.

24. The method of claim 11 wherein said categorization system comprises a plurality of categories, said plurality of categories comprising: documeot ID, page type, author of said document, specialization of said author, provider of the record, and date of said document.

25. The method of claim 24 wherein said selectioo criteria selects documents in a category of said plurality of categories.

26. The method of claim 11 further comprising, when needed, converting to electronic format each document of said patient's medical records.

27. The method of claim 11 further comprising, providing to said patient a Combined Medical Records (CMR) report, said CMR report comprising said categorized documents organized by sections, said sections comprising a clinical pages section.

28. The method of claim 27 wherein said clinical pages section comprises Medications & Allergies, Immunizations, Patient Intake Apps, Physical Exams, Progress Notes, Consultations, Operative Notes, ER Reports, Hospital Summaries, EKGs, Imaging Reports, Special Tests, Labs & Cultures, Therapy Notes, Billing & Insurance, and Other subsections.

29. The method of claim 11 further comprising, providiog to said patient a Medical Summary (MS) report, said MS report comprising said categorized documents organized by sections, said sections comprising a selected clinical pages section.

30. The method of claim 29 wherein said selected clinical pages sectioo comprises Medications & Allergies, Immunizations, Physical Exams, Progress Notes, Consultations, Operative Notes, ER Reports, Hospital Summaries, EKGs, Imaging Reports, Special Tests, Labs & Cultures, Therapy Notes, and Patient Added Pages sub-sections.

31. The method of claim 11 further comprising, searching for a doctor's location using a customized search engine.

32. A method for a patient accessing said patient's medical records originating from a plurality of healthcare providers, said method comprising:

collecting from said plurality of healthcare providers said patient's medical records;

categorizing a plurality of documents of said patient's medical records according to a categorization system;

storing in a storage area of a central computer storage said categorized plurality of documents, said storage area under control of said patient; and

displaying a document log of said categorized plurality of documents to said patient.

33. The method of claim 32 further comprising displaying a time line graph indicating a date when a document of said categorized plurality of documents was created.

34. The method of claim 32 wherein said document log comprises an inventory of said categorized plurality of documents sorted by document ID, page type, author of said document, specialization of said author, record provider, or document date.

35. The method of claim 32 wherein said document log is sorted by date in reverse chronological order.

36. The method of claim 32 wherein said document log comprises a link to a display of a document of said categorized plurality of documents.

37. A system for centrally managing a plurality of medical records of a patient distributed across a plurality of healthcare providers, said system comprising:

a collection module for collecting from said plurality of healthcare providers said plurality of medical records,

a computerized categorization system for categorizing each medical record of said plurality of medical records, wherein said categorization system is the same for all healthcare providers of said plurality of healthcare providers;

a patient directed central storage area for electronically storing said categorized plurality of medical records; and

a retrieval module for retrieving an ordered plurality of documents of said categorized plurality of medical records, wherein said ordered plurality of documents is arranged using at least one of a plurality of criteria, said plurality of criteria based on said computerized categorization system.

38. The method of claim 37 further comprising a display for displaying said ordered plurality of documents.

39. The method of claim 38 wherein said display for presenting comprises a Web browser.

40. The method of claim 37 further comprising a distribution module for creating a CD, email, facsimile document, or printed document comprising information in said ordered plurality of documents.

41. The method of claim 37 further comprising a search engine application stored in a computer readable medium for locating a doctor or an organization of said plurality of healthcare providers.

42. The method of claim 37 wherein said categorization system comprises: document ID, page type, author of said document, specialization of said author, provider of the record, and date of said document.

43. A method of centrally managing medical records of a patient authored by a plurality of healthcare providers, said method comprising:

collecting from said plurality of healthcare providers a plurality of medical records, wherein said plurality of medical records comprise a plurality of paper based documents, and wherein said plurality of healthcare providers comprise a past and a current health care provider;

classifying each page of said plurality of paper based documents using classes of a classification system common across said plurality of healthcare providers;

converting each page of said plurality of paper based documents to an electronic image;

storing each electronic image in a computer readable medium wherein access to said computer readable medium is authorized by said patient;

retrieving an organized subset of said electronic images, using at least one of a plurality of criteria; and

displaying an electronic image of said organized subset.

44. The method of claim 43 wherein said classifying each page comprises adding a header and a footer to each page, wherein said header comprises a first group of classes of said classification system and said footer comprises a second group of classes of said classification system.

45. The method of claim 44 wherein said first group comprises: a document ID, page type, patient name, and member ID.

46. The method of claim 45 wherein said page type is a medical category selected from a group consisting of: Medications & Allergies, Immunizations, Patient Intake Apps, Physical Exams, Progress Notes, Consultations, Operative Notes, ER Reports, Hospital Summaries, EKGs, Imaging Reports, Special Tests, Labs & Cultures, Therapy Notes, Billing & Insurance, and Other.

47. The method of claim 44 wherein said second group comprises:

author of said page, author's specialization, if a doctor, and creation date of said page.

48. The method of claim 43 wherein said classification system comprises: a document ID, page type, patient name, member ID, author of said page, author's specialization, if a doctor, and creation date of said page.

49. A system for centrally managing a plurality of medical records of a patient originating from a plurality of healthcare providers, said system comprising:

a backend server for receiving said plurality of medical records from said plurality of healthcare providers, wherein each document of said plurality of medical records is categorized;

a database connected to said backend server for storing said categorized documents, wherein access to said categorized documents is controlled by said patient; and

a Web server connected to said backend server and to a client system, wherein said Web server processes a search request by said client system for retrieving a set

of ordered documents of said categorized documents, said set arranged by using at least one of a plurality of criteria.

50. The system of claim 49 further comprising a scanner coupled to said backend server for converting a paper-based document of said plurality of medical records to an electronic image for storing in said database.

51. The system of claim 49 further comprising a search engine for locating a healthcare provider of said plurality of healthcare providers.

52. The system of claim 49 further comprising a window displaying a current collection status of a patient's medical records from a healthcare provider of said plurality of healthcare providers.

53. A method in a computer system for displaying a document log of a plurality of medical records of a patient, comprising:

displaying a table comprising a plurality of rows, wherein each row comprises a plurality of columns, wherein a column of said plurality of columns comprises a plurality of cells associated with a category of a plurality of categories; and

displaying document ID data in a cell of said plurality of cells of a row of said plurality of rows, wherein said document ID data identifies a document in said plurality of medical records.

54. The method of claim 53 wherein said plurality of categories comprises: document ID, page type, author of said document, specialization of said author, provider of the record, and date of said document.

55. The method of claim 53 wherein said document ID data comprises a hyperlink to an electronic image of said document, and wherein, when said hyperlink is selected, said electronic image is displayed.

56. A method, using a computer, for enabling a patient to comment on a medical record of said patient, comprising:

searching for an electronic image of said medical record using a category assigned to said medical record, said electronic image stored in a database, wherein access to said electronic image is controlled by said patient;

receiving a patient's comments; and

electronically linking said patient's comments with said electronic image.

57. The method of claim 56 further comprising displaying said patient's comments concurrently with said electronic image.

58. The method of claim 56 further comprising storing in said database said patient's comments, and retrieving said patient's comments, when said electronic image is displayed.

59. The method of claim 56 wherein said category is selected from a group consisting of document ID, page type, patient name, member ID, author of said document, specialization of said author, provider of the record, and creation date of said document.

60. The method of claim 56 further comprising:

receiving a doctor's comments; and

electronically linking said doctor's comments with said electronic image.

61. A method in a computer system for displaying to a patient a document timeline of a plurality of documents in a patient's medical records, comprising:

displaying a first axis having sequential calendar time units;

displaying a second axis listing said plurality of documents; and

providing an indication along said first axis of a creation date of at least one of said plurality of documents.

62. The method of claim 61 wherein said indication on said first axis includes a name of an author of said document and said date of creation.

63. The method of claim 61 wherein said listing of said plurality of documents is by medical sub-categories.

64. The method of claim 61 wherein a document of said plurality of documents comprises a document identifier, said document identifier comprising a hyperlink to an electronic image of said document, and wherein, when said hyperlink is selected, said electronic image is displayed.

65. The method of claim 61 wherein said calendar time unit is selected from a group consisting of day, month, and year.

66. A method in a computer system for displaying a progress note timeline of a plurality of progress notes in a patient's medical records, comprising:

displaying a first axis indicating sequential calendar time units;

displaying a second axis indicating a total number of said plurality of progress notes for each sequential calendar time unit; and

providing an indication along said first axis of said total number of said plurality of progress notes with creation dates in a calendar time unit of said sequential calendar time units.

67. The method of claim 66 wherein said calendar time unit is selected from a group consisting of day, month, and year.

68. A method for using a patient's medical records by a doctor, comprising clinical pages, stored in a patient directed computer storage area, said method comprising:

said doctor selecting a category of a plurality of categories categorizing said clinical pages;

retrieving from said computer storage area a subset of clinical pages, wherein said subset comprises a plurality of clinical pages belonging to said category and not designated private by said patient;

calculating an availability factor, wherein said availability factor is a ratio of a number of clinical pages belonging to said subset to a total number of clinical pages belonging to said category; and

displaying said availability factor to said doctor for use in evaluating completeness of said subset.

69. The method of claim 68 wherein said plurality of categories comprise a plurality of medical sub-categories of a page type category.

70. A method for using a patient's medical records by a doctor, comprising clinical pages from a healthcare provider,

stored in a patient directed computer storage area, said method comprising:

said doctor selecting a category of a plurality of categories categorizing said clinical pages;

retrieving from said computer storage area a subset of clinical pages belonging to said category;

calculating a source factor, wherein said source factor is a ratio of a number of clinical pages in said subset obtained directly from said healthcare provider to a total number of clinical pages in said subset; and

displaying said source factor to said doctor for use in evaluating reliability of said subset.

71. The method of claim 70 wherein said plurality of categories comprise a plurality of medical sub-categories of a page type category.

72. The method of claim 70 wherein said total number of clinical pages in said subset is a sum of clinical pages in said subset obtained directly from said healthcare provider plus clinical pages in said subset obtained via said patient.

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(54) SYSTEM AND METHOD FOR THE MANAGEMENT OF GENOMIC DATA

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(57) ABSTRACT

A system and method is disclosed for managing users' genomic data, including providing and offering access to genomic-based services, routing genomic data to providers of genomic-based services, brokering financial transactions related to the management of genomic data, securing for users best prices for genomic-based services, allowing users to earn money for the use of their genomic and other data, and using genomic data for marketing and developing products in particular geographic regions or for particular populations.

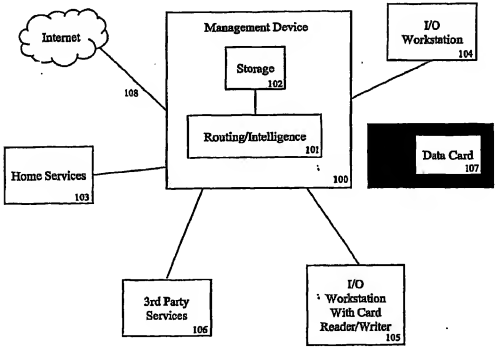


FIG. 1

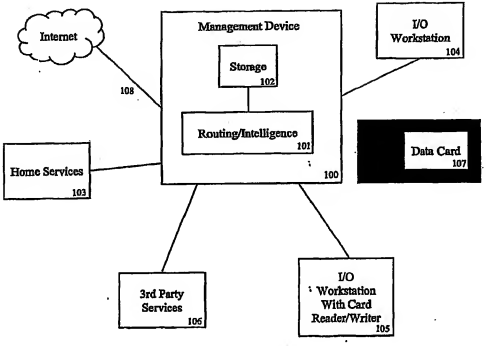

Internet
Management Device
Storage
102
I/O
Workstation
104
108
Routing/Intelligence
101
Data Card
107
Home Services
103
100
3rd Party
Services
106
I/O
Workstation
With Card
Reader/Writer
105

FIG. 2

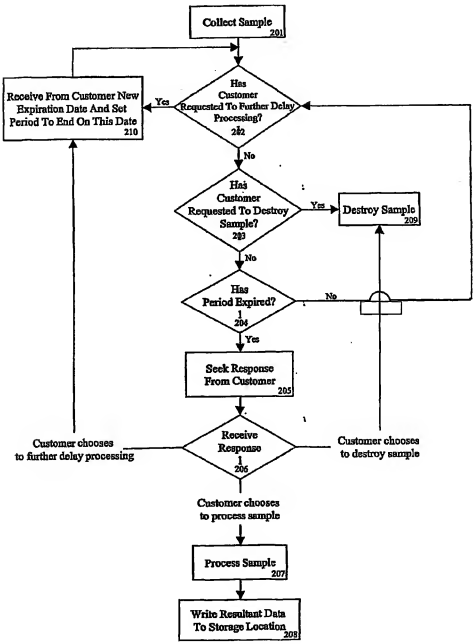

Collect Sample
201
Has Customer Requested To Further Delay Processing?
202
Yes
Receive From Customer New Expiration Date And Set Period To End On This Date
210
No
Has Customer Requested To Destroy Sample?
203
Yes
Destroy Sample
209
No
Has Period Expired?
204
No
Yes
Seek Response From Customer
205
Receive Response
206
Customer chooses to further delay processing
Customer chooses to destroy sample
Customer chooses to process sample
Process Sample
207
Write Resultant Data To Storage Location
208

FIG. 3

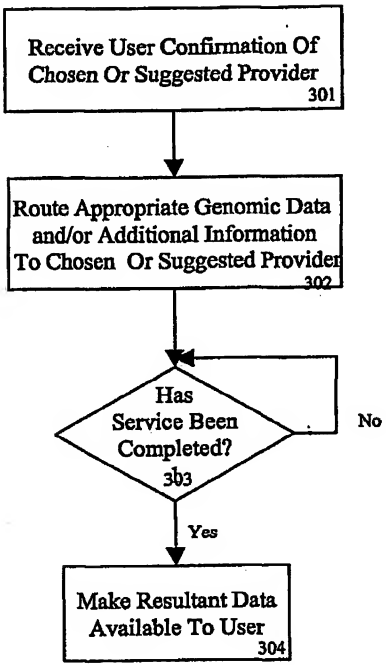

Receive User Confirmation Of Chosen Or Suggested Provider
301
Route Appropriate Genomic Data and/or Additional Information To Chosen Or Suggested Provider
302
Has Service Been Completed?
303
No
Yes
Make Resultant Data Available To User
304

FIG. 4

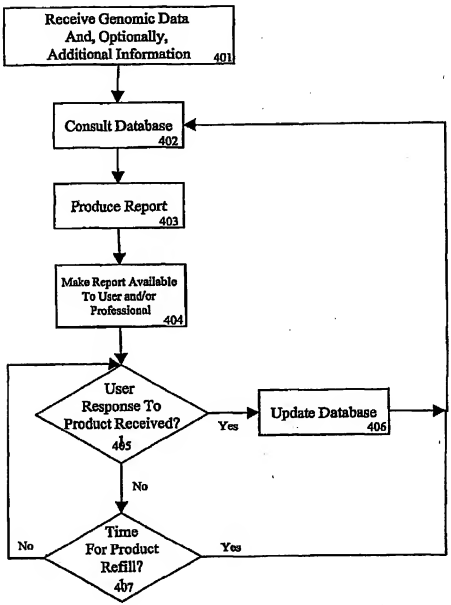

Receive Genomic Data And, Optionally, Additional Information
401
Consult Database
402
Produce Report
403
Make Report Available To User and/or Professional
404
User Response To Product Received?
405
Yes
Update Database
406
No
Time For Product Refill?
407
No
Yes

FIG. 5

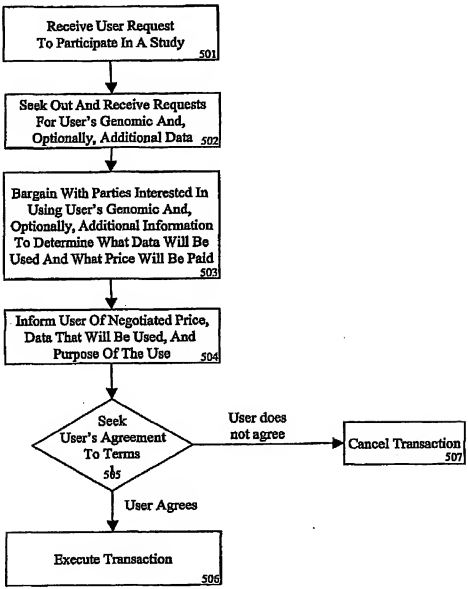

Receive User Request To Participate In A Study
501
Seek Out And Receive Requests For User's Genomic And, Optionally, Additional Data
502
Bargain With Parties Interested In Using User's Genomic And, Optionally, Additional Information To Determine What Data Will Be Used And What Price Will Be Paid
503
Inform User Of Negotiated Price, Data That Will Be Used, And Purpose Of The Use
504
Seek User's Agreement To Terms
505
User does not agree
Cancel Transaction
507
User Agrees
Execute Transaction
506

FIG. 6

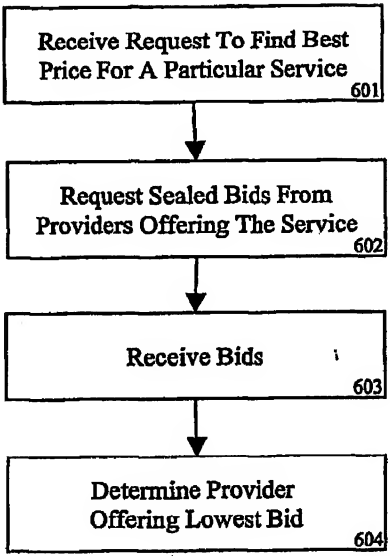
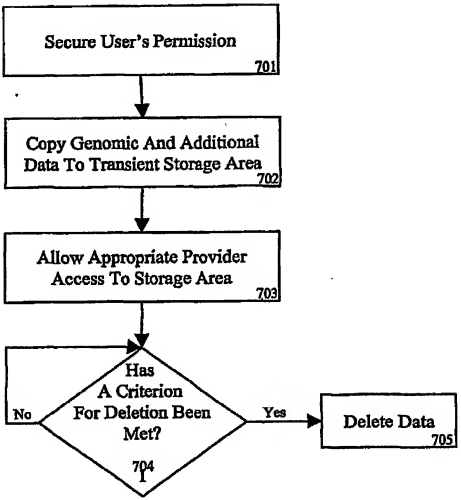

Receive Request To Find Best Price For A Particular Service
601
Request Sealed Bids From Providers Offering The Service
602
Receive Bids
603
Determine Provider Offering Lowest Bid
604

FIG. 7


Secure User's Permission
701
Copy Genomic And Additional Data To Transient Storage Area
702
Allow Appropriate Provider Access To Storage Area
703
Has A Criterion For Deletion Been Met?
704
No
Yes
Delete Data
705

SYSTEM AND METHOD FOR THE MANAGEMENT OF GENOMIC DATA

FIELD OF THE INVENTION

[0001] This invention relates to systems and methods for the management of genomic data and to the use of genomic data in developing and marketing products and services to consumers and the healthcare industry.

BACKGROUND OF THE INVENTION

[0002] Recent advances in the understanding of the human genome portend great potential benefit to the population at large. It is known, for example, that there are genetic markers that indicate susceptibility to certain diseases. If an individual learns of such a susceptibility through genetic testing, she may be able to alter her lifestyle to prevent or delay the disease's onset, or to ameliorate its effects. Genomic analysis can also be used to allow a couple to make an informed reproductive decision, by determining the likelihood of children of that couple inheriting a genetic disease.

[0003] Genetic variation among individuals has also been found to be relevant to their responses to pharmaceuticals. Correlations have been found between certain genetic markers, such as haplotypes, and responses to drugs. If such correlations were used to produce genetic-based prescribing information, then prescriptions could be written with an individual's genetic makeup in mind. This could improve individuals' lifestyles by lessening side-effects and increasing efficacy.

[0004] Non-medical uses of genomic data have also been found. For example, certain manufacturers of candy and cosmetics have become interested in how genetic diversity accounts for people's varying perceptions of taste and smell. This has the potential of allowing a person to purchase candy that is particularly appealing to her genetically-determined sense of taste.

[0005] However, despite the great potential benefits of doing so, few individuals have taken advantage of genomic-based services.

[0006] One reason for this is the public's concern for the security and privacy of its genomic data. People fear, for example, that they could be denied employment, denied insurance, and otherwise discriminated against if the details of their genomic makeup became public.

[0007] Another reason is convenience. With emerging Internet and communications technologies, people are used to being able to get information quickly and with little inconvenience. However, genomic-based services such as genetic testing have been heretofore inconvenient to use. For example, an individual may have to travel to a distant location for a test. If several tests performed at different locations were required, an individual would likely have to give a genetic sample to each location. Similarly, genomic-based prescription information is not available to patients and medical professionals in such a way that it can be unobtrusively incorporated into the average medical office or pharmacy.

[0008] Further, genomic-based services, such as tests for disease susceptibility, can be expensive. Individuals are used to enjoying low prices for products and services due to competition and the assistance of Internet services. However, such price-lowering has not yet come to genomic-based services.

[0009] Thus, for at least these reasons, advances in genomic knowledge have fallen short of realizing their potential benefits to the population.

SUMMARY OF THE INVENTION

[0010] In one aspect, the invention features a system and method for managing users' genomic data. Therefore, one object of the invention is to provide a system and method for providing and offering access to genomic-based services. Another object of the invention is to provide a system and method for routing genomic data to providers of genomic-based services. Still another object of the invention is to provide a system and method for brokering financial transactions related to the management of genomic data. A further object of the invention is to provide a system and method for securing a user a best price for a genomic-based service. Still another object of the invention is to provide a system and method for allowing users to earn money for the use of their genomic and other data. Still further objects of the invention are to provide a system and method for using genomic data to market a product in a geographic region of interest, and a system and method of using genomic data in developing new products to satisfy unmet demands or needs of a population.

[0011] Accordingly, in one embodiment the invention concerns a method for recruiting a new user for a genome management service, comprising obtaining a cell sample from a person, waiting a period of time, after the period of time has elapsed seeking from the person final permission to have his or her genomic data managed, analyzing at least a portion of the person's genome, and storing the resultant genomic data electronically. In a second embodiment the invention concerns a method for maintaining an individual's genomic data, comprising a data storage unit in which the individual's genomic data is stored and a self-destruct unit, which deletes the data on the device when a trigger event occurs. In a third embodiment the invention concerns a data card for maintaining an individual's genomic data, comprising a data storage unit in which the individual's genomic data is stored. In a fourth embodiment the invention concerns a method for providing product usage advice for an individual, comprising receiving the individual's genomic data, using the genomic data to consult a database or table which correlates genomic data with responses to products, and creating a report containing product usage advice for one or more products. In a fifth embodiment the invention concerns a method for producing marketing data, comprising receiving from a group of individuals their genomic data, receiving from the group of individuals data concerning their purchasing habits, determining correlations between the genomic data and the purchasing habits, and making a prediction concerning an individual's purchasing habits based on that individual's genomic data.

[0012] In another embodiment the invention concerns a method for marketing products to individuals based on their genomic data, comprising receiving from a group of individuals their genomic data, receiving from the group of individuals data concerning their purchasing habits, determining correlations between the genomic data and the

purchasing habits, making a prediction concerning an individual's purchasing habits based on that individual's genomic data, and making a product suggestion. In an additional embodiment the invention concerns a method of providing an individual with lifestyle advice related to his or her genomic data, comprising using an individual's genomic data to consult a database or table which correlates genomic data with information related to the genomic data, receiving, as a result of the consultation, information related to the genomic data, and providing lifestyle advice related to the information.

[0013] In yet another embodiment, the invention concerns a method of marketing a product in a geographic region of interest, comprising obtaining information relating to correlations between users' response to the product and a haplotype profile, determining the frequency of the haplotype profile in the population living in the geographic region, and making a marketing decision for the geographic region based on the determined frequency of the haplotype profile. In yet another embodiment, the invention provides a method for developing a new product to satisfy a particular unmet demand or need of a population, comprising identifying a haplotype profile that is correlated with the unmet demand or need in the population, determining a functional cause for the correlation between the haplotype profile and the unmet need or demand, and developing a new product designed to avoid the functional cause.

[0014] In still another embodiment the invention concerns a method of providing a gaming experience to an individual based on his or her genomic data, comprising receiving the genomic data of the individual and affecting gameplay using the genomic data, whereby the individual's gaming experience is due at least in part to his or her genomic data. In a further embodiment the invention concerns a method of designing products based on an individual's genomic data, comprising obtaining the individual's genomic data and creating a design for the product based on the genomic data. In another embodiment the invention concerns a method for marketing an individual's genomic data, comprising contacting a party interested in using an individual's genomic data, negotiating with the party to determine the terms of use for the data, seeking the individual's consent to allow the party to use the data under the determined terms of use, and if consent is received, providing, under the determined terms of use, the genomic data to the party.

[0015] In still another embodiment the invention concerns a method for providing an individual with low price genomic-based services, comprising receiving from the individual or his or her representative a request for a genomic-based service, negotiating with a plurality of parties capable of providing the service in order to determine which party of the parties is willing to offer the service at a lower price than the remainder of the parties, and upon receiving the individual's or representative's consent, allowing the party which offered the lower price to perform the service. In a further embodiment the invention concerns a billing method for a genomic data managing service, comprising charging a management fee and charging a fee for each access or update of the data. In an additional embodiment the invention concerns a method for providing an individual's genomic data, comprising receiving from a party a request for an individual's genomic data, negotiating with the party to determine the terms of use for the data, seeking the individual's consent to allow the party to use the data under the determined terms of use, and, if consent is received, providing, under the determined terms of use, the genomic data to the party.

[0016] Another embodiment of the invention concerns a method for securely transmitting an individual's genomic data to a party, comprising storing an individual's genomic data on a data card and physically transporting the data card to the party. Still another embodiment of the invention concerns a method for securely transmitting an individual's genomic data to a party, comprising creating one or more data packages containing the individual's genomic data and allowing the party to download the package over a network. A further embodiment of the invention concerns a method for allowing a user to make use of his or her genomic data, comprising receiving from the user a request for an operation he or she wishes to be performed making use of his or her genomic data and performing the operation.

[0017] The scope of the invention should not be considered as being limited by these objects and embodiments. Additional aspects, objects, and embodiments will become clear upon a reading of the disclosure and the claims that follow it.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] **FIG. 1** is a schematic diagram of a system according to one embodiment of the invention.

[0019] **FIG. 2** illustrates one embodiment of the process of adding a new user's genomic data to the system.

[0020] **FIG. 3** illustrates one embodiment of the process of fulfilling a user's request for a service.

[0021] **FIG. 4** illustrates one embodiment of the process of providing food, drug and nutritional supplement guidance.

[0022] **FIG. 5** illustrates one embodiment of the process of finding a best price compensation for use of a user's genomic or other data.

[0023] **FIG. 6** illustrates one embodiment of the process of securing for a user a best price for a particular service.

[0024] **FIG. 7** illustrates one embodiment of the process of allowing a service provider access to a user's genomic or other data.

DETAILED DESCRIPTION OF THE INVENTION

[0025] A. Definitions

[0026] The following definitions are used herein:

[0027] Candidate Gene—A gene which is hypothesized to be responsible for a disease, condition, or the response to a treatment, or to be correlated with one of these.

[0028] Genetic marker—A variation from a refrence genomic or mitochondrial DNA sequence that occurs in at least one individual in a population. As used herein genetic markers include polymorphisms, haplotypes, haplotype pairs, DNA methylation patterns, and other types of markers that are presently known or subsequently discovered.

[0029] Genotype—An unphased 5' to 3' sequence of nucleotide pair(s) found at one or more polymorphic sites in a locus on a pair of homologous chromosomes in an individual.

[0030] Haplotype—A sequence of nucleotides found at one or more of the polymorphic sites in a locus in a single chromosome of an individual.

[0031] Haplotype pair—The two haplotypes found for a locus in a single individual.

[0032] Haplotype profile—A combination of one or more haplotypes (or haplotype pairs) that are correlated with a particular phenotype, including consumer purchasing habits, disease susceptibility, drug therapeutic profiles, patient compliance with prescribed or recommended dosing regimens.

[0033] Locus—A location on a chromosome or DNA molecule corresponding to a gene or a physical or phenotypic feature.

[0034] Nucleotide pair—The nucleotides found at a polymorphic site on the two copies of a chromosome from an individual.

[0035] Polymorphic site—A nucleotide position within a locus at which the nucleotide sequence varies from a reference sequence in at least one individual in a population. Sequence variations can be substitutions, insertions or deletions of one or more bases.

[0036] Polymorphism—The sequence variation observed in an individual at a polymorphic site. Polymorphisms include nucleotide substitutions, insertions, deletions and microsatellites and may, but need not, result in detectable differences in gene expression or protein function.

[0037] Polymorphism data—Information concerning one or more of the following for a specific gene: location of polymorphic sites; sequence variation at those sites; frequency of polymorphisms in one or more populations; the different genotypes and/or haplotypes determined for the gene; frequency of one or more of these genotypes and/or haplotypes in one or more populations; any known association(s) between a trait and a genotype or a haplotype for the gene.

[0038] Polymorphism Database—A collection of polymorphism data arranged in a systematic or methodical way and capable of being individually accessed by electronic or other means.

[0039] Reference Population—A group of subjects or individuals who are predicted to be representative of the genetic variation found in the general population living in a defined geographic region. In preferred embodiments, the reference population represents the genetic variation in the population at a certainty level of at least 85%, preferably at least 90%, more preferably at least 95% and even more preferably at least 99%.

[0040] Single Nucleotide Polymorphism (SNP)—A polymorphism in which a single nucleotide observed in a reference individual is replaced by a different single nucleotide in another individual.

[0041] Therapeutic Profile—A plot of the response (e.g., level of efficacy and or number of adverse events) exhibited by a group of individuals to a particular drug or therapy.

[0042] Unphased—As applied to a sequence of nucleotide pairs for two or more polymorphic sites in a locus, unphased means the combination of nucleotides present at those polymorphic sites on a single copy of the locus (i.e., located on a single DNA strand) is not known.

B. DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0043] A system in accordance with an exemplary embodiment of the invention is shown in FIG. 1. A "management company", which manages people's genomic data and/or offers them genomic-based services, could operate a management device **100**. Management device **100**, as shown, consists of interconnected main components storage device **102** and routing/intelligence device **101**. In some embodiments, storage device **102** may be implemented using one or more secure servers or general purpose computers, while routing/intelligence device **101** may be implemented using one or more general purpose computers. In other embodiments, the functions of these two components may be combined into one component. For example, management device **100** may be implemented as one or more general purpose computers, with each computer providing the functionality of storage device **102** and/or routing/intelligence device **101**. Alternately, the functionality of these two components may be spread among two or more components. The phrases "general purpose computer" and "computer," as used herein, include, but are not limited to, an engineering workstation or PC. "General purpose computer" and "computer" also include, but are not limited to, one or more processors operatively connected to one or more memory units, wherein the memory may contain data, algorithms, and/or program code, and the processor or processors may execute the program code and/or manipulate the program code, data, and/or algorithms.

[0044] Management device **100** is connected to one or more I/O workstations **104** without data card interfaces, one or more I/O workstations with data card interfaces **105** (e.g., I/O workstations operatively connected to data card interfaces), one or more "home" genome-based services **103** provided by the management company, and optionally one or more genome-based services **106** provided by third parties. The I/O workstations equipped with card readers are capable of reading from, and in some embodiments writing to, data cards **107**. These connections may be made in a variety of ways well-known in the art such as using the Internet, private lines such as leased T1 lines, or a local or areawide wireless network. In the case where private lines are used, the management device may be additionally connected to the Internet as shown in connection **108**.

[0045] The I/O workstations may take several forms depending on the specific tasks they will be used for. For example, an I/O workstation used by a member to access home and third party services may be a web browsing device located in that person's home, such as a personal computer connected by the Internet. As a second example, an I/O workstation for entering a new sequence might be a browser-equipped engineering workstation connected to the Internet, further interfaced with a smart card reader/writer and laboratory equipment. As a third example, an I/O workstation in a physician's office, pharmacy, health food store, supermarket, restaurant, cyber cafe or the like might be a browser-equipped personal computer or computerized cash register

connected to the Internet, further interfaced with a smart card reader. Other embodiments of I/O workstations will be obvious to those skilled in the art in light of the remainder of this disclosure and its appended claims.

[0046] The genetic material of an individual who desires or is in need of having her genomic data stored, managed or analyzed for correlations with phenotype would first need to be submitted to the management company. Genetic material may be submitted by the individual who desires genomic services, or may be submitted by a skilled intermediary, such as a physician or physician's assistant. In a preferred embodiment, this genetic material would be submitted in the form of cells obtained during a cheek swab. Although other cell and tissue samples, such as fibroblasts or blood, would provide the needed genetic material, the cheek swab has the benefit of being painless and noninvasive. In certain embodiments, specific cell types will be obtained. For example, in some embodiments it might be desired to obtain B or T cells.

[0047] There are several conditions under which the cheek cells could be obtained. In one embodiment, the patient could perform the procedure in her own home. A kit could be provided which would include instructions and the materials needed for the obtaining and shipping the sample. In a preferred embodiment, the individual comes to a collection center where the sample will be collected by trained personnel. Such a scheme has several benefits, among which are not only ensuring a properly harvested sample, but also the trained personnel being able to provide information and emotional support to the individual. This support is important because much of the general population has many questions concerning genetic information, as well as fear concerning the privacy of this data.

[0048] In order to make it easy for individuals to submit their samples, sample collection centers could be set up in a number of locations. In one embodiment, collection kiosks could be set up in public areas like malls and airports. In another embodiment, a mobile collection van could travel to certain areas where people congregate. For example, the van might park outside a busy office building at lunch time. In a third embodiment, collection could be performed at the office of a healthcare professional such as a physician.

[0049] These collection centers could be "branded." In other words, the collection centers could have distinct colors, designs, interior layouts, exterior shapes, and the like. Such branding has several benefits, which are well known to those versed in the art. Among these are advertising, close binding of the company and its service, and establishing a corporate image. For example, designs could be chosen which make users feel that the company is "professional," courteous, and concerned about genetic privacy. When these designs are also distinctive, customers would be able to easily tell the company apart from its competitors. Such designs would also likely stick in people's minds, hence acting as a sort of advertising.

[0050] In some embodiments, the sample would be processed as soon as possible after collection. Such an embodiment could be employed, for example, when there exists an immediate medical need to make use of an individual's genomic data. In other embodiments, a period of time would elapse between collection of the sample and its processing. For example, this period of time could be one week. The customer, or her authorized agent such as her physician, could contact the service during this period of time to have the sample destroyed or to delay further processing. If the customer did not contact the service during this period of time, the company could contact the user at the end of the period seeking permission to have the genetic sample processed. The user could choose to grant permission, deny permission, or to delay processing. If the user denied permission, or no response was received from the customer, the sample could be destroyed.

[0051] Preferably, a user who chose to delay processing could choose to do so either indefinitely or until a certain date. If the user chose to delay until a certain date, the management company would contact the user on that date seeking permission to process the sample. At this time the user would again have the choice of granting permission, denying permission, or further delaying processing. If the user choose to delay indefinitely, the management company would store the sample until it received explicit instructions to process or destroy the sample. In some embodiments, the management company would contact the user periodically, asking permission to proceed. If the user did not answer, the sample would continue to be stored but would not be processed. In other embodiments, the company would not contact the user, but instead would wait to be contacted by the user. In certain embodiments, the user would be charged a fee for the storage service. For example, the user may be charged a monthly fee if the sample is stored without being processed for more than six months. Further, the management company may impose an upper limit on how long it would be willing to store the sample without processing it. For example, the management company might set as a policy that all samples which sit unprocessed for three years are destroyed.

[0052] Many customers are reluctant to make big decisions, and might be hesitant to join the service for fear they would regret the decision later. The "waiting period" would give customers opportunity to initially submit a sample without fear, knowing that they had a period of time in which to change their mind without any consequence, with the possible exception of being charged a small processing fee.

[0053] Once the "waiting period" elapses, and final consent is given, the genetic sample provided is processed so as to yield the individual's genomic data. Such genomic data includes, but is not limited to, data relating to the individual's genes, genotype, genomic sequence or a portion thereof, haplotypes or haplotype pairs, the data describing one or more of the individual's polymorphisms, such as SNPs and RFLPs, data describing B or T cell DNA rearrangements, and data describing DNA modifications, such as methylation. The term "genomic data," as used herein, also includes data from non-genomic DNA, such as data describing mitochondrial DNA. The processing may be done using conventional techniques well-known in the art. In some embodiments, individuals can either give final consent or have their consent presumed if they have not asked for the sample to be destroyed within a certain period of time. This processing may be performed by the management company or a third party under contract with the management company. The resultant genomic data can easily be stored on digital media. For example, the sequence of base pairs that makes up an individual's genomic sequence is effectively a string of

characters. The system will write to a storage location such resultant genomic data corresponding to a new user. In some embodiments, the user or her authorized agent can opt to have this data deleted at a later time.

[0054] FIG. 2 is a flow chart showing one exemplary embodiment of the above-described procedure. In step 201, the sample is collected. In step 202, it is determined if the customer has requested to further delay processing. If the customer has requested to further delay processing, flow proceeds to step 210 where the new expiration date is received from the user, and the period is set to end on this date. If the customer has not requested to further delay processing, flow proceeds to 203 where it is determined if the customer has requested to destroy the sample. If it is determined that the customer has requested to destroy the sample, flow proceeds to step 209 where the sample is destroyed.

[0055] If the customer has not requested to destroy the sample, flow proceeds to step 204 where it is determined if the period has expired. If the answer is "no," flow proceeds back to step 202. If the answer is "yes," flow proceeds to step 205 where a response is sought from the user as to whether he or she wants to further delay processing, to process the sample, or to destroy the sample. The response is received in step 206 and depending on the response, flow proceeds to step 210 (if the customer chooses to further delay processing), 207 (if the customer chooses to process the sample), or 209 (if the customer chooses to have the sample destroyed). In step 207 the sample is processed, after which the resultant data is written to a storage location (step 208).

[0056] In a preferred embodiment the party performing the processing of the sample, whether it be a third party or employees of the management company, would not know the identity of the individual who submitted the sample. One method of achieving this is for the management company to correlate a temporary identification number with the individual. Such a temporary identification number might include numerals, letters, or other characters.

[0057] This correlation may be done by generating a semi-random temporary identification number and associating this number in a lookup table with the individual's identity. "Semi-random" refers to the fact that the randomly-generated identification number might have to meet certain requirements in order to be acceptable, and if not found to be acceptable would be regenerated. For example, the system might require that the generated number not be one which is currently in use. In other embodiments, no lookup table would be used, and the correlation would be done using a cryptographic algorithm which would translate between actual identities and temporary identification numbers. Methods for formulating such algorithms, generating such semi-random numbers, and building such lookup tables are well known to those versed in the art.

[0058] This temporary identification number, but no personally identifying information, would be included with the genetic sample for submissinn to the party performing the processing. This party would return the resultant genomic data, along with the corresponding temporary identification number, to the management company. In some embodiments, the party may do this by entering the information into an I/O workstatinn 104. The management company, upon receipt of the information, would ascertain from the returned temporary identification number which individual's genomic data had been received. This ascertaining step might be done using a lookup table. In another example, this ascertaining step might be done using a cryptographic algorithm to decode the identification number into an actual identity. Next, the genomic data would be stored and the temporary identification number would be de-correlated from the individual so that the number could be reused.

[0059] Alternately, the sample may be delivered to the party performing the processing of the sample, and the resulting genomic data may be received therefrom, in a manner according to pending application Ser. No. 09/611,654 "Methods and Apparatus for Ensuring The Privacy and Security of Personal Medical Information" (filed Jul. 7th, 2000), incorporated herein by reference. This application discloses a method of ensuring the security of data from a medical test. The method includes providing the patient with a medical data card issued by a secure information provider, and having a unique patient identification number (PID), a public key encryption private key (Key 1), and a public key encryption public key (Key 2). The medical data card is used to generate a first test request card that accompanies the test specimen taken from the patient to the secure information provider. The first test request card includes an encrypted identification of the patient and the test, a code identifying the health care provider, the patient identification number, public encryption public key (Key 2), and an identification of the test type. The secure information provider uses the first test request card to generate a second test request card to forward the patient's specimen to a testing laboratory. The second test request card and the specimen are forwarded to the laboratory. The second test request card bears an encryption of the patient's unique identification number, but does not otherwise bear any indicia that would identify the patient. The laboratory performs the prescribed test and generates a first test results card. The results, together with the patient's unique identification number, are provided to the secure information provider that issued the medical data card. The secure information provider provides the encrypted test results onto a second test results card, and forwards the card to the health care provider. The test results on the second test results card are decrypted using the patient's medical data card. The methods described in this application could be used for the non-medical uses described herein as well.

[0060] In another embodiment of the invention, the genomic services requested of the management company relate to providing therapeutic guidance to an individual, or preferably her healthcare professional (e.g., physician, pharmacist, etc), in connection with the treatment of the individual for a particular disease or condition. In this case, the individual or her healthcare professional may submit a sample for processing as described above, or alternatively, the individual or her healthcare profession may already be in possession of the genomic data that is relevant to the advice being sought and such data is submitted to the management company who would perform, or have a third party perform, the requested genomic services. The delivery of the individual's genomic data to the management company may be done by any methods for securely transmitting data that are disclosed herein, as well as by other methods known in the art.

[0061] In one embodiment, all or part of the genomic data is stored on a secure server, such as storage **102**, preferably in an encrypted manner. In such a case, the genomic data that resulted from processing would be entered into or transferred to an I/O terminal **104**. The data would then be routed to secure storage **102** by routing/intelligence module **101**. Such routing could be achieved using signals. Secure storage **102** is managed by routing/intelligence **101** so as to carefully restrict who has access to an individual's genomic data, the guiding principle being that no one would have access to an individual's data without that individual's explicit permission. Optionally, information connecting an individual's identity to her genomic data may be separately stored, secured, and managed. In one embodiment, the genomic data would be stored in a secure database which correlated genomic data with identification numbers rather than with identities. A separate secure database, perhaps located at another location, would correlate the identification numbers with the actual identities. In another embodiment, a cryptographic algorithm would be used to translate between identification numbers and actual identities.

[0062] In another embodiment, all or part of the genomic data would reside on a data card **107** rather than on storage **102**. In such a case, the genomic data that resulted from processing is entered into or transferred to an I/O terminal with data card reader/writer **105**, and subsequently written to a data card **107**. In certain embodiments, this would be done so that the management company would not view or posses the genomic data. For example, the party processing the sample could directly write the resultant genomic data to the data card **107**. The party could than affix the temporary ID number to the outside of the card. The card would then be forwarded to the management company by secure messenger. Upon receipt of the card, the management company could, using the affixed temporary ID number, determine the user whose card has been received and forward the card to that user, perhaps by secure messenger. The management company could do this without accessing the contents of the card. In further embodiments, the party doing the processing could write the data to the card in an encrypted manner, wherein the key to unlock the data would be provided to the user but not the management company. In another embodiment, the management company could write the genomic data to the data card **107** through a secure network connection between the management company and an I/O terminal with data card reader/writer **105** located at the healthcare professional's office. In another embodiment, the data card **107** would include some or all of the individual's medical records, in particular information relating to the requested genomic services, e.g., medical history, diagnosis, clinical or physical measurements, adverse drug responses and the like. The genomic and medical information on the data card could be updated as further information becomes available.

[0063] Data card **107** would preferably be credit card sized so as to easily fit in an individual's wallet, billfold, purse, or the like. Several types of storage cards of this type exist. Among these are magnetic strip cards, "Smartcards," flash-memory cards, and the like. Smartcards are available from numerous venders, one such vender being Siemens of Munich, Germany. Preferably, personally identifying information such as the individual's name would neither be stored on the card nor printed on its exterior.

[0064] As one example of the functionality of data card **107**, a patient could go to her physician with a card encoded with her genomic data. The card could be swiped through a reader that taps into a database of drug information maintained by the management company or other service provider. The information could advise the physician which medication and/or which dose of a medication the patient should take—or avoid—for a particular illness, based on the person's genetic makeup. Alternately, the reader could be located at the patient's pharmacy and the pharmacist consults the drug information database in connection with filling a prescription written by the patient's physician. If the pharmacist receives any drug response information from the service provider that is inconsistent with the prescription, the pharmacist could communicate such information to the physician and request a revised prescription. In certain instances, the physician or pharmacist may be aware of a reason why the patient should take or avoid a particular drug. If so, that knowledge could optionally be added to the database. As researchers learn more about who is genetically likely to have a good or bad reaction to approved drugs, the database of drug information could be updated.

[0065] In another embodiment, the reader can comprise a handheld computer such as a Palm™ Handheld (manufactured by Palm Incorporated) or IPAQ™ Pocket PC (manufactured by Compaq Corporation). The physician may use the handheld device for other purposes, such as patient scheduling, accessing patient's records, taking notes, and the like. The hand-held computer may contain a database of drug information, or may be in communication with such a database operated by the management company or other service provider, either directly via a wireless connection or indirectly via a base unit station located in the physician's office or hospital. The base unit station could be connected to the database at the management company via the Internet or a private network or other type of direct link. At the end of the day, the physician may place the hand-held computer in the base unit station so that it can be recharged as well as upload data to and/or download data from the management company's database.

[0066] In a preferred embodiment, the storage card would be a smart card or a smartcard like device because of the extra features they provide. For example, smartcards have on-board processing units. Such extra features make it easier to add additional functionality to the data card. One example of such additional functionality would be a self destruct function by which the card would destroy its data under certain conditions. Examples of such conditions include the card being tampered with, an attempt to copy the card, an attempt to perform an unauthorized read of data from the card, and an attempt to perform an unauthorized write to the card. In another example, the processing unit of the card could perform encryption and decryption functions on board, a function of smart cards well-known in the art.

[0067] In another embodiment, the card could have the additional functionality of being able to operate in the manner of a credit card or bank card such that purchases could be made using the card. In still another example of additional functionality, a patient's medical record could be stored on the card, preferably in an encrypted format, in addition to her genomic data.

[0068] In an alternative embodiment, portable data storage devices other than cards can be used. For example, a

touch-memory device, such as the "i-button" produced by Dallas Semiconductor of Dallas, Tex. could be used. Such touch-memory devices can be easily incorporated into objects such as jewelry. Further, the data storage device may be implemented so that it communicates wirelessly with the routing/intelligence device. Such functionality could be achieved using IEEE 802.11 wireless networking technology, as well as using other wireless communication methods well-known to those versed in the art.

[0069] Although the data card represents an alternative to storing genomic data on storage device 102, in some embodiments the user could opt to have the information on his data card "backed up" on a storage device such as storage device 102. Preferably, the data would be stored in an encrypted manner. Further, such a backup vault would preferably not be connected to public networks, such as the Internet, so as to decrease the likelihood of data theft, tampering, and manipulation.

[0070] A function of the system is to provide users easy access to services based on their genomic data. Some of these services may be provided by the management company itself ("home services"103), others may be provided by third parties identified by or under contract with the management company, while still others could be offered by both.

[0071] In some embodiments, the user would have the option to download, receive or view her own genomic data. A user might wish to do this, for example, if she wished to do her own research on her genomic data. Further, the user may upload tests, programs, or algorithms which she wants performed or executed on her on data. For example, the user may write or execute a program which searches her genomic data for certain haplotype pairs. In another example, the user may write or execute a program which creates a musical rendition based on her genomic data.

[0072] In one embodiment, a user accessing the system through I/O workstation 104 for the purpose of using a service would be provided with menu options. This menu may take several forms, a preferred embodiment of which is a web page. An exemplary top-level menu is shown below:

[0073] Home Functions

- [0074] 1) Health and Life Style Advice
- [0075] 2) Games And Learning
- [0076] 3) Food, Drug and Nutritional Supplement Guidance
- [0077] 4) Genetic Tests
- [0078] 5) Participate in a Test—Medical
- [0079] 6) Participate in a Test—Non-medical
- [0080] 7) Purchase A Product based on your Genomic Data
- [0081] 8) Access Current Medical Information
- [0082] 9) Subscribe to Medical Information Updates

[0083] Third Party Functions

- [0084] 1) Genetic tests
- [0085] 2) Participate in a Test—Medical
- [0086] 3) Participate in a Test—Non-medical
- [0087] 4) Purchase A Product Based on your Genomic Data
- [0088] 5) Access Current Medical Information
- [0089] 6) Subscribe to Medical Information Updates

[0090] User Functions

- [0091] 1) View my Genomic Data
- [0092] 2) Receive my Genomic Data on an Encrypted Data Card, delivered by Secure Messenger
- [0093] 3) Download my Genomic Data to the Inserted Data Card or Other Media
- [0094] 4) Route my Genomic Data to a Specified Party

[0095] In such an embodiment, a user clicking on a menu option would be dropped to a lower level menu. Clicking on an option in the lower level menu might result in a still lower level menu, and so on until a final choice was chosen. For example, a user clicking on "genetic tests" would be given a choice of the available tests. After clicking on the desired test, the user would be given a menu listing providers of the test. In a preferred embodiment, prices would be listed next to each choice. Further, quality ratings may be listed next to each choice, perhaps using a rating system of one to four stars or a numerical ranking system which orders the providers based on quality. These ratings could be based on user feedback, expert evaluation, or the like.

[0096] In some embodiments, such user feedback and/or expert evaluation could be obtained by having a user and/or expert enter the feedback and/or evaluation into an I/O terminal connected to management device 100 via the Internet. For example, a user and/or expert could provide feedback and/or an evaluation by answering questions on a survey and returning it to the management company. In such embodiments routing/intelligence device 101 could route a survey from the management company to a user and/or expert's I/O terminal and, after the user and/or expert completed the survey using the I/O terminal, route the completed survey to the management company. In alternate embodiments, feedback, evaluations, and/or surveys could be transported between the management company and the expert or user using a courier. The survey would preferably include questions seeking both quantitative and qualitative information. For example, the survey could include questions concerning the accuracy of the service, as well as questions concerning whether the experience with the provider was a satisfactory one. Such a survey could be designed using methods well known in the field of surveys. For example, the survey could include alternate forms of questions which seek to obtain the same, or similar, answers. Inconsistent answers could be rejected and/or tagged for follow-up by the service provider for clarification or validation. Preferentially, the database would be updated in a manner that ensured the anonymity of the user.

[0097] In some embodiments, a quality seal of approval from a recognized authority which monitors compliance with certain standards could be listed next to providers which had been awarded the approval. In a further preferred embodiment "find the best price" and "find the provider with the highest quality rating" could be options on the menu of providers.

[0098] Upon the user selecting a provider, or a best price or quality provider being suggested to the user by the system, the system would ask the user to confirm the choice of selected or suggested provider. Preferably, this confirmation would involve the user entering a password or the like. In response to the user's confirmation, the system would route the user's genomic data to the appropriate service provider, be it the management company or a third party provider. Such routing could be achieved using signals. Depending on the service requested, the provider might require or prefer that additional information be provided in addition to the genomic data. For example, a provider who was to perform a genetic test for the user, or provide therapeutic guidance to the user's healthcare professional, might also require family history data, dietary data, medical data, lifestyle data, and the like. In such a case, the system would retrieve the required additional information and route it to the provider. In some embodiments the system would retrieve the additional information by having the user or her authorized healthcare professional enter it on her I/O terminal. In other embodiments, the system would retrieve the data from a secure database on storage unit **102**. In cases where additional information is to be sent to another party, the system seeks permission from the user, and does not send the additional information to the party unless permission is granted. In certain embodiments, the additional information could be compartmentalized so that only subsets of data could be retrieved, depending on the instructions of the user.

[0099] If the chosen service provider is a third party, the routing/intelligence module **101** routes the data to the appropriate third party **106**. Alternately, if the chosen service is a "home service" provided by the management company, the data is forwarded to the appropriate home service provider **103**.

[0100] Once the provider completes the service, the routing/intelligence unit makes the resultant data available to the user. In one embodiment, the intelligence unit would retrieve the results from the service provider and temporarily store them on storage device **102** in an encrypted format, and the system would notify the user that the results were available. The user could then download, decrypt, and view the results the next time she logged on to the system. In some embodiments, the user would have the option of transferring the results to her data card or I/O terminal. Once the results were transferred or read, they could be deleted from the storage device **102**.

[0101] In another embodiment, the system would not store the results. Instead it would notify the user that results were ready and available next time the user logged on. When the user logged on and requested the results, the intelligence module would route the results data from the provider directly to the user for reading or transfer to a data card or the like. In a preferred embodiment, the data would be routed in a secure and encrypted format. This embodiment may allay some users' fears of mishandling of their data, because the results would not even temporarily be stored on the system.

[0102] **FIG. 3** is a flow chart showing one exemplary embodiment of the above-described procedure. These steps may be performed, for example, by routing/intelligence device **101**. In step **301**, user confirmation of the chosen or suggested provider is received. Flow then proceeds to step **302** where the appropriate genomic data and additional information is routed (or provided) to the chosen or suggested provider, and then to step **303** where it is determined if the service has been completed. If the answer is "yes," flow proceeds to step **304** where the resultant data is made available to the user. If the answer is "no," flow returns to step **303**. In some embodiments, a provision may be made to cancel the service with the initially chosen provider and chose a new provider and route data to that new provider, for example, when the first provider is taking too long to complete the service. In such cases, the initially chosen provider's access to the data would preferably be revoked.

[0103] Notification of available results to the user could take several forms. For example, the system might flash a "results available" message the next time the user logged onto the system with an I/O terminal, or send an e-mail message. In another embodiment, the user could periodically call a telephone number to determine if her test was ready. In some embodiments, the number would connect to a live operator. In other embodiments, the number would connect to an automated voice system. In both cases, the user would preferentially have to enter a password to learn if her results were ready. In some embodiments additional security methods, such as voice print identification, may be used. In certain embodiments, the user could hear her test results via the telephone.

[0104] Alternately, the system might make a voice telephone call to the user using speech synthesis. In still another embodiment, the system might prompt a live telephone operator to call the individual and inform her that her test was ready. In some embodiments, the user would need to enter a password or to pass voice print identification before learning that a test was ready. In some embodiments, the user could choose to hear her results over the phone.

[0105] It is conceivable that in certain cases, due to illness or other factors, a user might be unable to retrieve her results and may wish to have a friend, family member, medical professional, or the like do it for her. In other cases, government regulation may require that the results be made available to a medical professional intermediary who is qualified to counsel the user as to the meaning and/or implications of the results. To provide such functionality, in some embodiments the user may specify additional parties who may access test results. A user would be able to designate such parties as being able to access the results of all tests, certain types or classes of tests, or one or more particular test instances. Further, parties may be granted conditional access. For example, a user may choose to grant her brother access to some or all of her test results, but only if she is critically ill or injured. In some embodiments, a user may choose that results could be protected using a fingerprint reader, such that results could not be accessed unless the user's finger, hand, or the like was placed in the reader. Such an embodiment could decrease the likelihood of unauthorized access to the results while, for example, allowing a physician to access results for an unconscious user by placing the user's finger, hand, or the like in the reader.

[0106] In another embodiment, the user of the system may be a medical professional, such as a physician or pharmacist, who is authorized by the patient to submit her genetic material or genomic data to the management company in connection with requesting genomic services relating to the

patient's healthcare. For example, a physician or pharmacist may seek therapeutic guidance from the management company relating to which drug or dosage regimen is likely to be optimal for a particular patient based on that patients' genomic data, and preferably medical data. The physician could then choose to use the therapeutic guidance received from the management company when prescribing a drug or other therapy for the patient and the pharmacist could use such therapeutic guidance in connection with filling a prescription. In another embodiment, the user of the system is the patient's healthcare payer, e.g., insurance company or health maintenance organization (HMO), who is authorized by the patient to access the system to determine if the most cost effective therapy has been prescribed for the patient. In this case, the healthcare payer might not be able to access to the patient's genomic data and would only be able to access information relating to the efficacy and/or safety of different treatment options.

[0107] It is further conceivable that a parent might want to have tests done for her minor child, infant, fetus, or the like. In certain embodiments, the system may allow the parent to choose which parties can request tests for the child and view the results of those tests. For example, a mother would be able to decide that she and her husband, but no other parties, would have the power to request tests and view test results.

[0108] As is alluded to by the sample top level menu, many genomic-based services are made available to the user. Each of these services could potentially be offered by a third party, the management company, or both. Many of these services employ databases or tables in which genomic data (including, but not limited to, haplotypes, haplotype pairs, SNPs, or methylation patterns) and/or additional information is correlated, perhaps statistically, with phenomena such as responses to foods or medications or susceptibility to diseases. For example, a database could correlate genomic data and/or additional information with responses to medications so as to produce a therapeutic guidance model, perhaps accessible via the Internet, that could be used by a physician for prescribing purposes.

[0109] In some embodiments, functionality could be added for updating these databases, for example, by using feedback such as feedback evaluating the quality and/or accuracy of the provided service. For example, a service provider whose database correlated genomic data and responses to food might, after reporting to a user a potential reaction to a food, ask the user what her actual response was. The user's reported response, along with her genomic data and/or additional information, could be used to update the database. In some embodiments, such feedback could be obtained by having a user, expert and/or professional enter the feedback into an I/O terminal connected to management device **100** via the Internet or private network. For example, a user, expert and/or professional could provide feedback by answering questions on a survey and returning it to the management company. In such embodiments routing/intelligence device **101** could route a survey from the management company to a user, expert and/or professional's I/O terminal and, after the user, expert and/or professional completed the survey using the I/O terminal, route the completed survey to the management company. In alternate embodiments, evaluations, and/or surveys could be transported between the management company and the user, expert and/or professional using a courier. The survey would preferably include questions seeking both quantitative and qualitative information. For example, the survey could include questions concerning the accuracy of the service and/or advice given, as well as questions concerning whether the experience with the provider was a satisfactory one. Such a survey could be designed using methods well known in the field of surveys. For example, the survey could include alternate forms of questions which seek to obtain the same, or similar, answers. Inconsistent answers could be rejected and/or tagged for follow-up by the service provider for clarification or validation. Preferentially, the database would be updated in a manner that ensured the anonymity of the user.

[0110] In further embodiments, functionality could be added for dealing with database "misses." For example, a user seeking advice from a service provider whose database correlated genomic data and responses to food might, for example, ask about a food which was not processed in the database. This would constitute a database "miss." As a result, the service provider might process collected genomic data and collected responses to various foods, find correlations between the genomic data and responses to the food which was not in the database, and add data concerning response to the food to the database. In other cases, in response to a database miss an expert may be contacted, for example, if a user's request for disease susceptibility information from a service provider led to a database miss, the service provider might employ the services of a genetic disease expert to answer the user's query and/or update the database. In some embodiments, service providers may employ algorithms which act upon, or take as input, all or part of a user's genomic data. In some embodiments, service providers may use one or more devices to perform the above-described tasks such as employing algorithms, contacting genetic experts, and updating, maintaining, and consulting databases. Such devices may include general purpose computers known in the art, such as PC's and engineering workstations. In some embodiments, these devices would be connected to management device **100**, perhaps via the Internet.

[0111] Genomic and related services described herein that employ databases may make use of the teachings of pending PCT International Application PCT/US00/7540 "Methods for Obtaining and Using Haplotype Data" (filed Jun. 26th, 2000; WO 01/01218), incorporated herein by reference. This application discloses methods, computer programs and databases to analyze and make use of gene haplotype information. These include methods, programs, and databases to find and measure the frequency of haplotypes in the general population; methods, program, and database to find correlation's between an individuals' haplotypes or genotypes and a clinical outcome; methods, programs, and databases to predict an individual's haplotypes from the individual's genotype for a gene; and methods, programs, and databases to predict an individual's clinical response to a treatment based on the individual's genotype or haplotype. Similarly, such services may employ the teachings of pending PCT International Application PCT/US01/12831 "Method and System for Determining Haplotypes from a Collection of Polymorphisms" (filed Apr. 18, 2001; WO 01/80156), incorporated herein by reference. This application discloses methods, computer programs and databases for identifying the haplotypes that exist in a population and methods,

programs and databases for predicting an individual's haplotype for a gene from the individual's genotype for that gene.

[0112] As was illustrated in the above example, one example of a service is a genetic test which returns a result explaining a susceptibility to a disease. Another such service is a "custom product" service.

[0113] A custom product service produces products based on one's genome. An example of this would be the production of music, jewelry or clothing whose design is derived from an individual's genomic data. For example, one-of-a-kind tee shirts or quilts could be designed by employing an algorithm that created a unique graphic based on a person's genomic data. Alternately, the shirts or quilts could be designed by accessing a database which correlates graphic designs or design components with genomic features such as haplotypes. A further example of a custom product would be a food that was produced so as to be especially appealing to the purchasing individual's genetically-determined sense of taste, as indicated by her genomic data. To achieve this, the service provider might, for example, maintain a database correlating, perhaps statistically, the presence of certain haplotypes or haplotype pairs in ones genome with liking certain flavors or textures. The service provider, upon receiving a food or meal request, would use the user's genomic data to consult the database in order to create a food or meal that the purchaser was likely to enjoy.

[0114] A similar example of a custom product would be a food or meal that was produced so as to be particularly appropriate for the purchasing individual's genetically-determined nutritional needs. In this case, the service provider might, for example, maintain a database correlating, perhaps statistically, the presence of certain haplotypes or haplotype pairs in one's genome with certain dietary needs. The service provider, upon receiving a food or meal request, would use the user's genomic data to consult the database in order to create a food or meal that would be a good fit for the purchaser's nutritional needs. In some embodiments, recipes and menus for the food or meal would be provided to the user. Alternately, the food or meal could be prepared for and delivered to the user.

[0115] Still another example of a custom product would be a musical composition that was designed so as to be especially appealing to the purchasing individual's genetically-determined sense of what is aurally pleasing, as indicated by her genomic data. To achieve this, the service provider might maintain a database correlating, perhaps statistically, the presence of certain haplotypes or haplotype pairs in one's genome with liking certain musical styles or constructions. The service provider, upon receiving a musical composition request, would consult the database in light of the user's genomic data in order to create a musical composition that the purchaser was likely to enjoy.

[0116] In some embodiments, functionality could be added for updating the database and/or algorithm, for example, by using feedback such as feedback evaluating the appeal of the provided product, using methods such as those described above, including surveys. Preferentially, the database would be updated in a manner that ensured the anonymity of the user.

[0117] Another service illustrated in the exemplary web page menu is for a user to access current medical information or subscribe to medical information updates. For example, a user may choose to access current or up-to-date medical information such as scientific articles, news articles, lectures, and films about diseases, drugs, nutritional supplements, and the like. Such information could be provided online, by e-mail, by physical delivery or other methods. A user choosing to subscribe to such information might, for example, select to receive each week all scientific articles relating to a specific disease. In some embodiments, users may choose to receive information based on their genomic data and/or additional information. For example, a user might choose to receive each week all scientific articles relating to the genetic diseases for which, according to her genomic data and/or additional information, she is at risk. In such an embodiment, the system could determine which articles would be appropriate for the user by consulting a database in which genomic data and/or additional information was correlated with increased likelihood of certain genetic diseases. In some embodiments, functionality could be added for updating the database, for example, by using feedback such as feedback evaluating the appropriateness of the provided articles, using methods such as those described above, including surveys. Preferentially, the database would be updated in a manner that ensured the anonymity of the user.

[0118] Still another service illustrated in the exemplary web page menu is for a user to route her genomic data to a Specified Party. For example, a user might use this feature to route her genomic data and/or additional information to a service provider not listed on any of the web page menus.

[0119] Also as seen in the sample web page menu, another service is for the user to participate in a test. One example of this would be a test run by medical researchers (including, but not limited to, a clinical trial), while another would be one run by market researchers. This is another case where the provider might require that additional information be routed along with the genomic data. For example, for a market researcher the additional information might be the food preference of the user. Such a provider's goal may be to statistically correlate food preference with the presence in the genome of certain markers. On the other hand, for a medical researcher, the additional information might be information relating to childhood illness suffered by the individual, the individual's lifestyle activities, or the individual's dietary habits. As is the case with all of the services, this service could conceivably be provided by the management company, a third party, or both. The system may provide for reimbursement of the user in exchange for the information as well as payment of a processing fee to the management company.

[0120] Another example of genomic-based services are games in which gameplay is based on and/or affected by a user's genomic makeup. For example, a multi-player game might employ an algorithm by which the player's genomic data would change the gameplay scenario, manipulate on-screen images, produce audible events, give game characters strengths or weaknesses (including illnesses) or otherwise affect the player's capabilities, or determine team assignment. In some embodiments, functionality could be added for updating the algorithm, for example, by using feedback such as feedback evaluating the appeal of the gameplay experience, using methods such as those described above,

including surveys. Preferentially, the database would be updated in a manner that ensured the anonymity of the user.

[0121] Still another example of a genomic-based service is to provide health and lifestyle information and guidance on various topics based, at least in part, on a person's genomic data.

[0122] For example, a person choosing "health and lifestyle advice" from the main menu might be shown the below sub-menu:

[0123] 1) What diseases do I have a genetic propensity for, and what preventative steps can I take now?

[0124] 2) What is a recommended diet for me?

[0125] 3) What is a recommended exercise program for me?

[0126] 4) What sports would I be best at?

[0127] 5) What genetic risks would my children face based on my genomic data and/or family history?

[0128] 6) (Two users only) What genetic risks would our children face based on our genomic data and/or family histories?

[0129] To execute such selections, a user's genomic data, along with any necessary additional information such as the user's weight, age, and family history, could be considered by using a database which correlates genomic data, and in some cases additional information, with lifestyle advice. Such lifestyle advice might include advice on taking preventative steps against the onset of a genetic illness or a condition to which an individual is genetically predisposed, diet recommendations, exercise recommendations, or the like. For example, a consultation of the database may yield the advice that the user should stop smoking because she is prone to arteriosclerosis.

[0130] In alternate embodiments, the database would correlate genomic elements, and in some cases "additional information," with information concerning diseases, lifestyle outcomes, and the like instead of advice. In such an embodiment, the system would need to take additional steps to provide advice related to this information. In one embodiment, a second database could be used to yield the actual advice. For example, a consultation or the first database may show that the user is prone to arteriosclerosis. This information may be used to consult a second database, which would yield the advice that the user should stop smoking.

[0131] For example, a user might ask about what sports she would be best at. A consultation of the database in light of her genomic data might yield the answer that she had a higher than average percentage of white muscle tissue and thus would be better at sports that require sprinting than endurance. The system might also recommend appropriate exercises if she were more interested in improving her performance in other types of sports. Another user, asking "What diseases do I have a genetic propensity for, and what preventative steps can I take now?" might learn that he was particularly susceptible to the effects of cigarette smoking and should quit immediately. In some embodiments, the system could provide estimated risks, which could vary as further information was obtained and integrated into the database.

[0132] In certain embodiments, two users could jointly ask a question of the system and have their genomic data jointly compared. For example, a couple planning on having children could have their genomic data jointly compared so that they could determine what genetic risks their planned children would face.

[0133] This service would provide more functionality than simple genomic testing, because results would preferably not just be a simple "yes" or "no" but would include lifestyle advice. In some embodiments, a counselor would be on call (by phone, on-line, etc.) to answer any questions the user had about the results provided by the database. In preferred embodiments, the results provided by the database would be "dynamic". This is to say that the results provided would change as more information were obtained from various sources (such as users) and analyzed. A related service provides users with trivial information concerning their genomes. For example, a user who selected from the menu system the question "what's genetically unique about me?" might learn that she lacked a psoas minor, one of the five muscles of the human body which are most frequently absent.

[0134] In some embodiments, functionality could be added for updating the database, for example, by using feedback received in connection with previously provided genomic services such as feedback evaluating the accuracy and/or utility of the provided health and/or lifestyle information and/or guidance, using methods similar to those described above, including surveys. For example, a survey could include questions concerning the accuracy of health and/or lifestyle information and/or guidance given, as well as questions concerning whether the provided information lead to a perceived lifestyle improvement and answers to these questions could be used to update the database. Preferentially, the database would be updated in a manner that ensured the anonymity of the user.

[0135] Still another service is a food, drug and nutritional supplement guidance service. In one embodiment, a user, preferably working with her physician, pharmacist, or nutritional supplement expert selects "Food, Drug and Nutritional Supplement Guidance" from the menu system of an I/O terminal. Such an I/O terminal, perhaps connected to management device 100 via the Internet, could be located in a physician's office, health food store, or pharmacy, so that the genetically-guided prescription or usage suggestion of drugs and nutritional supplements could be unobtrusively incorporated into clinical or pharmaceutical practice or store operation.

[0136] The user's genomic data, along with necessary additional information such as the proposed prescription or usage suggestion and perhaps demographic information such as the user's weight, age, and family history, is then considered in light of the content of a database. The database preferably correlates genomic data (such as haplotypes, haplotype pairs, SNPs, methylation patterns, and the like), and perhaps certain additional information, with responses to specific over-the counter drugs, prescription-only drugs, nutritional supplements, and similar products. In preferred embodiments, the database can be updated as new information is obtained. Using the result of the database consultation, the system creates a report with product and dosage advice, adverse reaction warnings, and the like.

[0137] In some embodiments, the routing/intelligence unit would, as above, make the report available only to the user. It would be the user's responsibility to pass the report to the physician, pharmacist or nutritional supplement expert.

[0138] In other embodiments, the user's doctor or pharmacist receives the report, but has no access to any genomic data of the patient. Preferably, the physician or pharmacist would receive the report after accessing the system using the pharmacy or medical office I/O terminal and entering a password. In still other embodiments, the report would be delivered to the physician or pharmacist, but in such a manner that it could not be read by the physician or pharmacist without the presence or consent of the patient. For example, the user might need to enter a password on the medical office I/O terminal in order to allow the physician or pharmacist to view the report. In another embodiment, the user's consent or presence would be determined by taking the user's fingerprint, voiceprint or retinal scan. Alternatively, the patient might choose to entrust the physician or pharmacist with the password. In certain embodiments, there may be different passwords for access to different information or data. For example, the system may create or allow the use of a password which offered a physician access to results of a test that she ordered for a user, but to no other information regarding that user. In another embodiment, the physician or pharmacist would be able to access the report without the user's permission, e.g., if the report was deemed critically necessary for providing appropriate medical treatment to an unconscious or mentally incapacitated user or to a relative of a deceased user.

[0139] In a preferred embodiment, when it is time for a product refill, the database is re-consulted and a new report is created so that the prescription can be changed to reflect any updated genomic-based prescription advice.

[0140] In some embodiments, the user, doctor, pharmacist, or other professional could forward the patient's actual drug reaction to the service provider so that the database could be updated to take into account the reported drug reaction when giving future advice. The service provider could use this information to refine statistical correlations of drug responses with genomic data and/or other data. Preferentially, the database would be updated in a manner that ensured the anonymity of the patient. In certain embodiments routing/intelligence device 101 could forward the patient's reaction from the professional to the service provider. Such behavior could be achieved, for example by having the professional enter the reaction into an I/O terminal connected to management device 100 via the Internet. In some embodiments, the professional would report the drug reaction by answering questions on a survey and returning it to the service provider. In such embodiments routing/intelligence device 101 could route a survey from the service provider to the professional's I/O terminal and, after the professional completed the survey using the I/O terminal, route the completed survey to the service provider. In alternate embodiments, results and/or surveys could be transported between the service provider and the professional using a courier.

[0141] The survey would preferably include questions seeking both quantitative and qualitative information. For example, the survey could include questions concerning actual physical test results or responses, as well as questions concerning whether the response was sufficient for the physician to decide to maintain the patient on the drug. Such a survey could be designed using methods well known in the field of surveys. For example, the survey could include alternate forms of questions which seek to obtain the same, or similar, answers. Inconsistent answers could be rejected and/or tagged for follow-up by the service provider for clarification or validation. Further, the report could be updated at the time the product was refilled. This update could be based on additional information which was added to the database since it was last consulted, such as the user's response to the prescribed product and dose, the user's response to other product, as well as information from other users or other sources. Preferentially, the database would be updated in a manner that ensured the anonymity of the user.

[0142] In additional embodiments, the food, drug and/or nutritional supplement guidance report may not only give information for a drug or nutritional supplement chosen by a physician or pharmacist, but may also suggest that a different product be used. For example, a physician may ask for a food, drug and nutritional supplement guidance report for drug A for a particular patient. The consultation of the database would yield not only potential lack of efficacy or adverse reactions, but also the advice that Drug B would be a better choice based on one or more of the patient's genetic profile, lifestyle information, and other additional information.

[0143] In further embodiments, a physician, pharmacist or other professional would not have to submit a proposed prescription. Instead, the professional would submit, or request the retrieval from storage of, any required additional information such as diagnostic values, symptoms, and/or a diagnosis of the patient's condition. Based on the genomic data and any additional information, a profile would be created which would suggest one or more drugs, preferably noting for each one a suggested dose and/or efficacy rating. In a preferred embodiment, probable side effects would also be listed.

[0144] For example, a physician may submit, or request the retrieval from storage of, a patient's blood lipid level, age, gender or other relevant information relating to a patient's cardiovascular disease. The report created based on this information and the patient's genomic data might contain the prediction that the patient had a 90% chance of responding to a first lipid-modulating drug, a 80% chance of responding to a second lipid-modulating drug, and a 20% chance of responding to a third lipid-modulating drug, along with a dosage suggestion for each drug. The physician would then be able to choose which of the three drugs she wished to use for the patient. For example, the physician may choose the second drug if it is in a hospital's formulary, or the patient's HMO formulary, but the first drug is not.

[0145] In one embodiment, a physician may choose to prescribe to a patient a particular drug or dosage regimen for such drug even though the report predicts that the patient will exhibit an adverse response to that drug or dosage regimen. In this case, the physician would monitor the patient for the adverse response while on the drug, and afterwards, if medically appropriate. Because an adverse response to the drug may affect the patient's compliance with the prescribed dosage regimen, the physician may also choose to more closely monitor how and when the patient is consuming the drug.

[0146] FIG. 4 is a flow chart showing one exemplary embodiment of the operation of the above-described food, drug, and/or nutritional supplement guidance service. These steps may be performed, for example, by a general purpose computer. In step 401 an individual's genomic data, and optionally additional information, is received. In step 402, the database is consulted. Next a report is produced (step 403) and made available to the user and/or a professional assisting the user (step 404). In step 405, it is determined if the user's (and/or other user(s)') response to the product has been received. If the answer is "yes," flow proceeds to step 406 where the database is updated using the user's (and/or other user(s)') response and then returns to step 402, where the database is consulted and an updated report is produced based on data incorporating the user's (and/or other user(s)') response. If the answer in step 405 is "no," flow proceeds to step 407 where it is determined if it is time for a product refill. If the answer is "yes," flow proceeds to step 402. If the answer is "no," flow proceeds to step 405.

[0147] In a second embodiment, the food, drug, and nutritional supplement guidance service would operate in a manner similar to the first embodiment, the main difference being that it would provide advice concerning the use of foods instead of drugs and nutritional supplements. In one instance of this embodiment a user, preferably working with a nutritionist or healthcare professional, would submit a suggested food, menu, or diet, along with any necessary additional information, in the manner discussed in the first embodiment. Alternately, this embodiment is compatible with a food market or restaurant environment wherein a clerk, server, or the like would enter a proposed meal or food purchase along with any necessary additional information into an I/O workstation located on the premises. The submitted genomic and additional information would be considered in light of a database which correlated genomic data with dietary restrictions and dietary guidance, and an advisory report would be created.

[0148] In a third embodiment, the food, drug and nutritional supplement guidance service would operate in a manner similar to the first two embodiments, but the I/O workstation used to enter data would be in the form of a computerized cash register or similar device located in a food market, health food store, pharmacy, restaurant or the like. Alternately, the I/O workstation could be a web browser used to make online purchases. This embodiment could provide genetically-guided point of sale advice concerning the purchase of food, drugs, nutritional supplements and other products.

[0149] For example, a mother whose child had PKU (phenylketonuria) might attempt to purchase for her child a soft drink bottle at a store whose cash registers functioned as I/O workstations. The child's genomic data, along with perhaps additional information, would be considered in light of a database that correlated genomic data and perhaps additional information with responses to foods and other products. As a result of the database consultation the system might advise the mother that the purchase was not advised because the soft drink contained phenylalanine, a substance which would be harmful to the child due to her genetic makeup.

[0150] This point of sale embodiment could also advise users against the purchases of foods they were allergic to or that were problematic for reasons such as inborn errors of metabolism, or advise against the purchase of over-the-counter drugs or nutritional supplements which were not ideally genetically compatible or were genetically problematic. In some embodiments, the system could suggest alternate foods, drugs, or other products that were more genetically compatible or less genetically harmful than the products that the user was attempting to purchase.

[0151] Still another function of the system is to broker financial transactions related to management of genomic data. In order to implement this feature, the routing/intelligence device 101 could execute one or more of the below-described billing schemes. Billing records could be held on the storage unit, while monetary transfer could be achieved using electronic finds transfer (EFT) and credit card billing techniques well known in the art.

[0152] In one aspect, individuals storing their genomic data in the system may be charged a fee by the management company for various actions. For example, individuals may be charged a fee for collection and/or processing of their biological sample so as to yield genomic data. Individuals may further be charged a fee for initially establishing a management account and/or a fee for maintaining the account. The latter fee, for example, might take the form of a monthly or annual fee. Individuals may also be charged for further processing of their DNA or initial sample, or for processing of an additional sample, to yield additional genomic data. For example, a fee may be charged to a user who had initially paid to have only five genes or haplotypes recorded as her genomic data, but later chose to have additional genes or haplotypes recorded. Similarly, users may be charged for adding, deleting, or otherwise revising non-genomic data. In embodiments of the invention which use data cards, individuals may be charged an initial issue fee for a data card, and another fee if the card is lost or damaged and needs to be replaced.

[0153] Fees may be charged for the routing of genomic data and/or other information to service providers, both third party providers and those run by the management company. For example, in some embodiments an individual may be charged a fee when the system routes her genomic data to a service provider. If the service provider is a third party, the third party, instead of the individual, may be charged the fee. In still other embodiments, both the third party provider and the individual are charged. In other embodiments, the management company may pay a fee or credit the account of a user for use of her genomic or other information.

[0154] In some embodiments, users may opt to pay a one-time fee rather than being charged for various actions and/or for having their genomic data and/or other information routed to service providers. For example, a one-time fee might entitle a user to have her sample collected and processed, her management account established and maintained for life, and her genomic data and/or other information routed to service providers without additional cost. In some embodiments, there may be limitations to what one is entitled to after paying a one-time fee. For example, the payment of the one-time fee might entitle one to a certain number of routings a year with additional routings being available for an extra cost.

[0155] Further, fees may be charged for the services themselves. For example, for services provided by third

parties, the system may act as an intermediary and collect money from the individual on behalf of the third party. In preferred embodiments, the third party would be charged a fee for this billing and collection service. For "home services" provided by the management company, the management company may directly bill the individual. For example, home services which provide lifestyle advice might charge a fee for each piece of advice given. Games may charge a fee per play, or per unit of time the game is played. As a further example, fees may be charged for system functions related to food, drug and nutritional supplement guidance profiles. For example, a fee may be charged for each profile created. This fee may be charged to the individual, the medical or other professional, or both.

[0156] In some embodiments, drug companies may be charged fees when a drug is prescribed on the advice of a food, drug and nutritional supplement guidance profile. For example, a drug company may be charged a "finder's fee" if a drug is chosen by a doctor on the advice of a food, drug and nutritional supplement guidance profile. For example, a physician may ask for a food, drug and nutritional supplement guidance profile for drug A, produced by company X, for a particular patient, and be advised that Drug B, produced by company Y, would be a better fit based on the patient's genetic profile. If the company X were different from company Y, company Y may be charged a "finder's fee" if there was a business agreement between company Y and the management company.

[0157] In other embodiments, a healthcare payer (e.g., a health insurance company or HMO) may only reimburse a healthcare provider, or its insured patient, for service fees or drug costs that are incurred in connection with the insured's medical treatment if the healthcare provider prescribes or dispenses a drug or therapy that is predicted to provide the patient with the most medically- and/or cost-effective care based on the patient's genomic data. Thus, for example, if the patient has cardiovascular disease and is in need of a statin and is predicted to have less severe side effects or a greater reduction in LDL-cholesterol to statin A than statin B, an insurance company or HMO would only reimburse the healthcare provider for the patient's care in regard to cardiovascular disease if the healthcare provider prescribes or dispenses statin A to the individual. In another embodiment, the healthcare payer may not require that the healthcare provider prescribe the best drug for the individual (based on the individual's DNA) but one of the better drugs. For example, if the individual is in need of a reduction in cholesterol, and drugs A, B, C, and D are each predicted to cause a 20%, 24%, 32% and 5% decrease, respectively, in cholesterol in the individual, an insurance company or HMO may reimburse the health care provider (or the patient) if the individual is prescribed drug A, B or C, but not D.

[0158] In some embodiments, the level of medical- and cost-effectiveness of certain therapies that qualifies for reimbursement may be specified in the patient's contract with the healthcare payer. In other embodiments, whether the level of efficacy and/or safety predicted for a proposed therapy qualifies for reimbursement may be determined on a case by case basis by the healthcare payer in consultation with medical experts and/or with the insured's healthcare provider. In another embodiment, the insurance company or HMO may only reimburse the healthcare provider (or the patient) if the patient is prescribed or receives a drug that the management company recommends for the patient based on the patient's genomic data and preferably other patient information relevant to providing therapeutic guidance. The invention contemplates that this recommendation may be transmitted by the management company directly to the healthcare payer, who in some embodiments, may pay the management company a fee for such transmittal.

[0159] In yet another embodiment, a drug may be indicated for individuals with a certain haplotype profile, and the insurance company would only reimburse the health care provider (or the insured individual) for prescription or purchase of the drug if the insured individual has that haplotype profile. The presence or absence of the haplotype profile in a patient may be ascertained by using any of the genomic services described herein or by the performance of a genetic test that is designed specifically for determining whether a patient belongs to the genetically-defined population that is part of the approved indication for the drug.

[0160] In all the above embodiments, the healthcare provider may be a physician, group of physician's, hospital, clinic, nurse or physician's assistant. In other embodiments, the healthcare provider may be a pharmacy, pharmacist, or other entity that dispenses medications to individuals.

[0161] The system also includes methods of facilitating the earning of money by users. In such embodiments, the system may, in response to an individual's request to earn money by participating in a study, seek out or receive requests from one or more third parties interested in using some or all of an individual's genomic data and/or other information for purposes such as research. For example, the intelligence module might maintain a list of pharmaceutical companies, academic institutions, or contract research organizations and periodically e-mail the research directors or other appropriate personnel of these institutions to learn what sort of research participants are currently being sought. Alternately, the management company might advertise itself in medical and scientific journal as a "clearing house" for research participants. In such a case, research groups seeking participants would contact the management company or intelligence module that is requesting participants with certain characteristics.

[0162] The system bargains with the third parties to decide upon the fee the third party will pay for the use of the genomic data and/or other information of a particular user. This is especially effective in cases where more than one third party is interested in using the data and/or other information, but only one will be awarded use. The brokering might include not only negotiation of price to be paid, but also amount of genomic data and/or other information used. For example, a third party might initially request information about three of an individual's haplotypes, but as result of the negotiation it might be bargained that only two would be used.

[0163] In some embodiments, once the system had come up with a highest price for the use of an individual's genomic data or other information, the system would inform the individual of how much money she would get, what specific data or other information would be used, and the purpose of the use. The system would seek the user's agreement, and would not execute the transaction with the third party unless agreement was received.

[0164] In alternate embodiments, the system notifies an individual of a research project seeking participants, informs

the individual of the nature of a research project and of the data being sought, and asks the individual if she is interested in having a place in the project negotiated for her, and if so under what conditions. For example, the user might state the condition that she was only interested in participating if she would receive at least $100, or that she was only willing to allow 5 of the 10 requested haplotypes to be used. The system would take such conditions into account during the bargaining process. In some embodiments, users could set default values concerning the conditions under which they would be interested in entering a research project. For example, an individual might set as her default profile that she only wanted to participate in medically-related projects related to a particular disease, such as breast cancer, or projects in which she would receive at least $75.

[0165] Preferably, as above, once the system had come up with a best-price for the use of an individual's genomic data and/or other information, the system would seek the user's agreement, and would not proceed unless agreement was received. Alternately, however, a user may agree ahead of time to participate in the project so long as her minimum conditions were met. It is understood that, in some cases, higher prices could be paid to the participating users when there is a high level of participation by other users, or approval to use more genomic data or other information that initially estimated. For example, it could be provided that the fee paid to an individual will increase as the amount of data she provided increases or the level of participation by other users increases.

[0166] In preferred embodiments, the system would charge for its negotiation services. In one embodiment, the system would take a percentage of the money agreed to be paid, while in other embodiments the system would take a flat fee equal to a certain amount of money. Such monies could be collected from the individual, the third party, or both. In some embodiments, the individual or third party might be allowed to choose between the two charging models, preferably before the result of the auction was announced to the user. In some embodiments, the management company might accept access to a provider's services in lieu of money owed to it by that provider.

[0167] FIG. 5 is a flow chart showing one exemplary embodiment of the above-described procedure. These steps may be performed, for example, by routing/intelligence device 101. In step 501, a user's request to participate in a study is received. In step 502, requests are sought out and received for the user's genomic and, optionally, additional information. In step 503, the parties interested in using the user's genomic data and, optionally, additional information are bargained with in order to determine what data will be used and what price will be paid. In step 504, the user is informed of the negotiated price, the data that will be used, and the purpose of the use. In step 505, the user's agreement to the proposed terms is sought. If the user does not agree, flow proceeds to step 507 where the transaction is canceled. If the user does agree, flow proceeds to step 506 where the transaction is executed.

[0168] As noted above, in some embodiments the system works to find the best price for a particular service when that service is offered by more than one provider. In one embodiment, the intelligence module 101 requests "sealed bids" from each of the providers offering the service. The intelligence module then selects the lowest bid, and forwards this information to the user. Alternately, the system could request that the user name the price she wanted to pay. The system would then forward this information to the providers offering the service, and see if any were willing to provide the service for the noted price. Other auctioning methods of securing a fair market price will be apparent to those skilled in the art. In certain embodiments the system might consider the quality of the providers when finding the best price for a particular service, perhaps by considering quality rankings or seals of approval. In some cases, a user could specify quality requirements when requesting that the system find a best price for a service. For example, a user could specify that she wants the best price among providers with a quality rating of three or more stars. Additionally, the management company could set quality requirements that could be applied to all user requests to find the best price for a service. For example, the management company might decide that the system would, when finding a best price for a customer, only consider providers who had been granted seals of approval. In further embodiments, the management company may charge the user for the service of having been secured a fair market price, charge the provider for the service of having found them a customer, or charge both parties. FIG. 6 is a flow chart showing one exemplary embodiment of this procedure. These steps may be performed, for example, by routing/intelligence device 101. In step 601, a request is received to find a best price for a particular service. In step 602, sealed bids are requested from providers offering the service, and in step 603 the bids are received. In step 604, it is determined which provider is offering the lowest bid.

[0169] As noted above, some embodiments of the data card allow it to be used to make purchases. Such functionality can be easily implemented by the system because it can perform conventional EFT and credit card billing functions in performing the abovementioned financial transactions.

[0170] In the embodiments of the data card that include financial transaction capability, users might be able to earn money points if they allowed the management company to anonymously record information concerning their purchases. Such information could be recorded, for example, each time a user makes a purchase using her data card. The goal in doing so would be to create databases correlating genomic data such as haplotypes and purchasing or consumption habits. In some embodiments, product and/or purchasing suggestions could be made based on these correlations. These suggestions could be offered to the users. The management company could construct the database in such a way that no personally-identifying information would be included. In this way the user's anonymity would be maintained. In some embodiments, the management company would sell its suggestions and/or statistical correlations, or the use thereof, to third parties. In some embodiments, routing/intelligence device 101 may be configured to perform these functions.

[0171] In some embodiments, functionality could be added for updating the database, for example, by using feedback such as feedback evaluating the appeal of a suggested product or the accuracy of the provided statistical correlations, using methods described above, including surveys. For example, the survey could include questions concerning the accuracy of the correlations, as well as

questions concerning whether the suggested product was appealing. Preferentially, the database would be updated in a manner that ensured the anonymity of the user.

[0172] Other embodiments might provide this functionality without the use of a data card with financial transaction capability. For example, in some embodiments the purchasing information could be recorded at a cash register and forwarded to the management company physically or electronically. In other embodiments, users may submit their own purchasing information, perhaps by filling out a questionnaire or by submitting copies of store purchase receipts. Such submission could also be done electronically or physically.

[0173] In other embodiments, the user could give permission for her identity and genomic data relating to her purchasing habits to be disclosed to third parties.

[0174] As alluded to above, a further function implemented by the system is to route an individual's genomic data, and any appropriate additional information, to a provider of a requested service, such as a third party provider or the management company.

[0175] As explained previously, a guiding principle behind this function is that an individual's genomic data may only be used by another party with the individual's permission. Accordingly, in preferred embodiments, care is taken that these parties never hold or posses a patient's genomic data, that they are not allowed to download the data, and that they are only allowed to use it for the purposes agreed upon and for the duration of time agreed upon. Further, it is preferred that a party does not know the identity of the individual to whom it is providing a particular service.

[0176] In certain embodiments, when the management company owns or runs service providers such as for providing the service of correlating an individual's genomic information with drug response, these service providers will face the same restrictions as third party service providers. For example, in preferred embodiments, while certain personnel of the management company will have access to user identities, steps will be taken so the personnel that work in a service provider division of the management company, in other words personnel responsible for performing services, will not know the identities of individuals to whom they provide services. Further, while the management company may store genomic data, it is preferred that service provider divisions of the company will not be allowed to download and keep the data. Thus, in certain embodiments, the genomic data shall be secured by appropriate internal safeguards so that it is only used for authorized uses by appropriate personnel.

[0177] In order to meet this goal, special techniques are used for the transmission of genomic and/or other data. In a first embodiment, service providers access the genomic data via a transient storage area on storage device **102**. In a second embodiment, the service provider downloads a "self-destructing" data package containing the genomic data in an encrypted format. In a third embodiment, the service provider physically receives a "self-destructing" data card containing the genomic data. In a fourth embodiment, the service provider reads the data directly from the data card during the period of time which the card is in the reader. Each of these embodiments will now be discussed in detail. Other embodiments are apparent to those skilled in the art.

[0178] In an example of the first embodiment, once permission has been secured the genomic data and any additional information is copied to a "transient storage area" to which the service provider is granted access. In a preferred embodiment, a temporary identification number corresponding to the user and a description of the service requested is also copied to the transient storage area. By use of a temporary identification number, the service provider does not know the identity of the individual for whom the service is being performed.

[0179] In embodiments where the genomic or additional information is stored on a data card, the user places her card in an I/O terminal with card reader **105**. The data is copied from the card to the transient storage area.

[0180] In embodiments where the genomic or additional information is stored on storage device **102**, this copying may be actual or virtual. In the actual case, the data is copied to the transient storage area and the service provider is given access to this transient area In the virtual case, the data is not moved from or copied from the original storage area, but instead the service provider is given expiring access to the original storage area.

[0181] In preferred embodiments, the service provider could only access the data through an active connection, and would be prevented from downloading the data. One method for achieving this would be set restrictions on the file so that it could be read but not copied or written to. Such file restrictions are used in most modern computer operating systems, and thus the methods for implementing them are well known in the art. Further, the data could be encoded in such a way that it would check where it was stored before allowing access to itself. Thus, if it were somehow downloaded to a storage location other than the one it was intended to be stored on, it would not allow itself to be accessed. Techniques such as this are well known in the art, as they are used to ensure, for example, that a program licensed to run on a specific computer only runs on that computer.

[0182] The temporary identification number functionality may be implemented in a manner similar to the disclosed method for ensuring anonymous processing of the initial genetic sample. Thus the management company may generate a semi-random temporary identification number and associate this number in a lookup table with an individual's identity. Alternately, a cryptographic algorithm may be used. As described above, the service provider would have access to the temporary identification number, the genomic data, any additional information, and description of the requested service. The service provider would return the results of the service, along with the corresponding temporary identification number, to the management company. The management company, upon receipt of the information, would ascertain from the returned temporary identification number which individual's service results had been received. The results would then be made available to the individual, and the temporary identification number would be de-correlated from the individual so that the number could be reused.

[0183] The phrase "transient storage area" emphasizes the fact the system will delete, or otherwise render unreadable, the data in this storage area under a number of circumstances. For example, the data might be deleted after a certain date has been reached or a certain period of time has

elapsed. The data might also be deleted if the service provider attempts to copy it. Further, in cases where the genomic data is stored on a data card, the data might be deleted upon removal of the card from the card reader. The data might also be deleted if the service provider attempts to handle the data in a manner other than the one agreed upon. For example, the data might be deleted if the service provider attempted to perform tests on it other than those agreed upon. In this way, the individual could feel assured that his genomic data would only be used for the purposes she agreed to and the service provider would be prevented from having permanent possession of the user's data. **FIG. 7** is a flow chart showing one exemplary embodiment of the above-described procedure. These steps may be performed, for example, by routing/intelligence device **101**. In step **701** the user's permission is secured. In step **702**, the user's genomic data and additional information is copied to the transient storage area. In step **703**, the appropriate provider is allowed access to the storage area. In step **704** it is determined if a criterion for deletion has been met. If the answer is "yes," flow proceeds to step **705** where the data is deleted. If the answer is "no," flow proceeds to step **704**.

[0184] In the second embodiment, the system would copy the genomic and additional information in the manner disclosed for the first embodiment. However, instead of the data being copied to a transient storage area, a "self-destructing" data package containing the data is created by the system. In preferred embodiments, the identification number and the description of the service requested are also placed in this data package. The system allows the service provider to download this package. The phrase "self-destructing" refers to the fact that the package is capable of deleting itself, or otherwise rendering the data that it carries unreadable. There are a number of circumstances under which the data would self-destruct. These circumstances may include the sample circumstances that led to deletion of data from the transient storage area in the first embodiment. For example, the package might be set with an expiring-self-destruct. In such a case, the package would destroy its data after a certain date had been reached or a certain period of time had elapsed. The data might also be set to self-destruct if the service provider attempted to copy it. Further, in cases where the genomic data is stored on a data card, the data might be set to self-destruct upon removal of the card from the card reader. In these ways, the service provider would be prevented from having permanent possession of the user's data. Further, the package might be set to self-destruct if the service provider attempted to handle the data in a manner other than the one agreed upon. For example, the data might self destruct if the provider attempted to perform tests on it other than those agreed upon. In this way, the individual could feel assured that his genomic data would only be used for the purposes she agreed to.

[0185] To deal with the eventuality of the package being intercepted in transport, additional self-destruct events could be added. For example, the package could have its data stored in an encrypted format, and be programmed to "self-destruct" if an incorrect key were applied to it. Further, the package could be programmed with a "self-destructing countdown timer". In such an embodiment, when the card was shipped a self-destruction countdown timer would be set, perhaps for 12 hours. When the service provider claimed receipt of the package, the management company would give the service provider a code with which to "defuse" the self-destruction countdown. Hence, if the package were intercepted in transport, the interceptor would not know the code with which to defuse the countdown, and thus the data on the card would self-destruct after the allotted time elapsed. Such a self-destruction countdown timer should not be confused with the above described expiring-self-destruct feature. An important difference between the two is that the countdown timer can be "defused," while the expiring-self-destruct cannot.

[0186] The third embodiment is like the second, but the data package is not made available to the service provider for downloading. Instead, it is placed on a data card that is physically delivered to the service provider.

[0187] Such a "self-destructing data card" would preferably be a smart card or some other card with on-board computing abilities. The on-board computational device would be programmed with a series of events that should result in "self-destruction" of the data, as well as with a self-destruct routine. These events would include, among others, those described in connection with the above-described self-destructing data package. The computational device would watch for these events, and when one occurred the processor would execute a routine which would delete the card's data contents. In preferred embodiments, the card would also have the features of the above-described permanent data card. For example, the card would preferably have its data stored in an encrypted format, with the card's on-board processor handing the decryption process.

[0188] Thus, in practice, the genomic data, and any additional information, would be loaded onto the self-destructing data card. The self-destructing data card would be physically delivered, preferably via a secure carrier or messenger, to the service provider. Preferably, the data would be stored in an encrypted format for which the service provider would be given a "key". In this way if the card were intercepted in transport, or someone took improper possession of the card, the contents of the card would be inaccessible.

[0189] In the fourth embodiment, the service provider reads the genomic data, and perhaps additional information, directly from a data card. Thus, the provider only has access to this data during the period of time for which the card is in the card reader. Once the card was removed from the reader, access would no longer be possible.

[0190] In one scenario, the card reader would be located at the third party's physical location, and the individual would go there to insert his card. In another scenario, the individual would insert the card at a reader distant from the third party, such as a reader-equipped I/O terminal **105**, and the service provider would read the data from the card via a secure and preferably encrypted network connection. Preferably, the card reader would capture or otherwise lock the card into place in a manner that it could only be removed from the reader by the owner of the card. In this way the individual could go to a card reader location, insert her card, and retrieve it at a later time.

[0191] In one embodiment, the identification number corresponding to the user and a description of the service requested could be delivered to the provider using one of the first three embodiments, while the genomic data itself would be made available using the method of the fourth embodiment. If the provider required additional information which

was not on the data card, the provider might receive this data by having the user enter it on an I/O terminal 105. Alternately, the additional information could be delivered to the provider using one of the first three embodiments.

[0192] As in the above embodiments, "self-destruct" procedures could be set up to protect the data. For example, the additional information could be sent as a self-destructing data card, and the personal data card would destroy its data if the service provider executed one of the above-described self-destruct events.

[0193] Alternately, instead of the personal data card destroying its data, it could instead leave its data intact but cut off the provider's access to it. For example, if the third party attempted to access the data more times than was agreed upon, the provider's access to the card would be cut off, but the card would remain undamaged so as to not inconvenience the owner. In other embodiments, the card would shut off not the provider's access to the card, but all read access to the card. In such embodiments the user would have to reactivate the card to make it functional again, perhaps by inserting it into an I/O terminal with card reader and entering a secret reset code.

[0194] In these embodiments, the data is preferably encrypted such that the service provider needs a key to access the data In some embodiments, each service provider is periodically provided a unique "period key" which will be used to decode all data that the provider is to access during that period. For example, the provider may be given a key each month which is to be used to decode all data during that month. In some embodiments the period key would be transmitted via a secure, encrypted transmission. For example, a security officer at the service provider might have a master key that can be used to decrypt the period keys that are provided. In other embodiments, the period key could be delivered physically by bonded messenger.

[0195] In some embodiments, the provider may be given a multitude of keys at once. The multitude of keys could be stored in a lookup-table which associates keys with code words. In such an embodiment, the service provider might receive from the management company a daily e-mail or daily physical letter via bonded messenger which contains the code word of the day. For example, the service provider might be informed that "today is an AZSDEFE" day. The service provider would feed "AZSDEFE" into the lookup table in order to receive the day's key.

[0196] In still other embodiments, the keys would not be sent to the service providers at all. Instead, each provider could be given a algorithm for creating the keys. The management company could use corresponding algorithms to encode data meant to be read by each provider. For further security, the key-generating algorithm could be a "black box" in the eyes of the service providers, which is to say they would not know how the algorithm worked. These methods provide only examples, and other methods known to those versed in the art for encryption and the providing of keys may be used as well.

[0197] In yet another embodiment, the invention concerns a method of marketing a product in a geographic region of interest, comprising obtaining information relating to at least one correlation between users' positive response to the product and at least one haplotype profile, determining the frequency of the haplotype profile in the population living in the geographic region, and making a marketing decision for the geographic region based on the determined frequency of the haplotype profile. As used herein, the term "marketing" means any activity associated with advertising, offering to sell and selling goods or services. The product may be any good or service for which there is a perceived need or demand in a particular geographic region. Preferably, the good or service is medically related, and more preferably the good or service is a drug or biologic, either of which may be previously approved by an appropriate regulatory agency, may be the subject of a pending application for regulatory approval or may be marketed without regulatory approval.

[0198] The geographic region of interest may be defined in any one of a number of ways, e.g., by the official or unofficial boundaries of a town, city or section thereof, county, state, multi-state region (e.g., in the United States, the Northeastern, Midwestern, Southern or Western region) country or continent. In one embodiment, the geographic region of interest may be a territory serviced by a healthcare provider such as an individual pharmacy or a pharmaceutical chain. In other embodiments, the geographic region of interest may be a territory serviced by a healthcare payer.

[0199] The response to the product includes any type of response exhibited by the user or consumer of the product that indicates the product will at least meet the perceived need or demand for such a product in the geographic region, and preferably indicates this need or demand will be met in a way that is superior to the performance of other products marketed in that geographic region for the same need or demand. In preferred embodiments, the product is a drug or biologic and the response to such a product is the therapeutic profile exhibited by the population present in the geographic region of interest or by a suitable reference population therefor.

[0200] Information relating to the haplotype profile correlation may already exist at the time this marketing method is being performed; such preexisting information might be obtained from a provider of genomic services such as the management company described herein. Alternately, obtaining such correlation information requires performing a new study that is designed to identify any correlations between genetic variation and product response that may exist in the population living in the geographic region. The entity seeking to market the product could conduct this study by itself or could contract the performance of this study with another party, e.g., the management company described herein.

[0201] The frequency of the correlated haplotype profile(s) in the population in the targeted geographic region may be determined by consulting preexisting genomic data for that population, or a reference population therefor, or by independently testing individuals for the presence or absence of the haplotype profile. The genetic testing may be performed for either most or all individuals of the population of interest to directly determine the frequency of the haplotype profile. Alternately, the haplotype profile frequency in the population of interest may be indirectly determined, or estimated, by the frequency of the haplotype profile that is directly determined for a suitable reference population. As above, the seeking to market the product may determine the frequency of the haplotype profile in the population of

interest or may contract with another party, e.g., the management company described herein, to determine this frequency information.

[0202] The marketing decision is based on the determined frequency of the haplotype profile in the population living in the geographic region of interest and may include a decision to market the product to the geographic region if the frequency of the haplotype profile correlated with a positive response to the product indicates that the product will achieve a sufficient level of market penetration in the targeted geographic region to meet the business goals and/or profit objectives of the entity seeking to market the product in that region. Alternately, if the frequency of the haplotype profile indicates the product will produce low sales in the geographic region of interest, the marketing decision may be to not proceed with marketing the product in that geographic region.

[0203] In yet another embodiment, the invention provides a method for developing a new product to satisfy a particular unmet demand or need of a population, comprising identifying a haplotype profile that is correlated with the unmet demand or need in the population, determining a functional cause for the correlation between the haplotype profile and the unmet need or demand, and developing a new product designed to avoid the functional cause. Examples of unmet demands or needs to which this invention may be applied include but are not limited to weight management, addictions to harmful substances such as nicotine, alcohol and other drugs, and diseases that are not being adequately treated in the population of interest by existing drugs or therapies.

[0204] To identify a haplotype profile that is correlated with an unmet demand or need, the frequency of haplotypes for one or more genes in a first population having the unmet need or demand is compared with the frequency of such haplotypes in a second population that either lacks the same need or demand or in which existing products satisfy that need or demand. This frequency information may be obtained using any method known in the art, including those described or incorporated by reference herein, or may be obtained from a genomic data management company such as described herein. The genes evaluated may primarily be those that are candidate genes for the unmet need or demand, or may constitute all genes known to exist in the genome.

[0205] Any haplotype or combination of haplotypes that is significantly higher in the first population than in the second population is a haplotype profile that may be selected to evaluate in the next step of the method, which is identifying a functional cause for the correlation between that haplotype profile and the unmet need or demand. For example, where the unmet need is a disease that is not adequately treated by existing drugs in the first population, the functional cause may be a haplotype in the haplotype profile that defines an isoform of the target for the existing drugs that has poor binding characteristics for such existing drugs. Or, the functional cause may be a haplotype in the haplotype profile that causes the bearer of that haplotype to be a poor metabolizer of these existing drugs, which may lead to lack of efficacy and/or undesirable side effects.

[0206] Once the functional cause for the correlation between the haplotype profile and unmet need or demand is determined, a new product may be designed to overcome the functional cause. For example, if the functional cause is poor drug binding characteristics for the isoform of the drug target that is present in the first population, then new candidate compounds for treating the disease may be identified by screening against that isoform of the drug, or alternately, a different target and drug combination with potential efficacy in treating the disease may be sought. Similarly, if the functional cause is the presence of a "poor metabolizer haplotype" in the haplotype profile, a new candidate drug metabolized by another metabolic enzyme or via a different pathway may be evaluated for its ability to overcome this functional cause and thereby meet the unmet need or demand.

[0207] The invention further provides a method for marketing a drug for inclusion in a formulary controlled by a healthcare provider or healthcare payer. Nonlimiting examples of the healthcare provider and payer are hospitals and HMOs, respectively. In one embodiment, the method comprises identifying a haplotype profile that is correlated with a good therapeutic profile for the drug, determining the frequency of the haplotype profile in the population served by the formulary and making a marketing decision based on the determined frequency of the haplotype profile. In one embodiment, the marketing decision is to pursue inclusion in the formulary if the frequency of the haplotype profile indicates that a significant percentage of the population served by the formulary will exhibit a better response to the new drug than drugs currently in the market, which may include drugs already in the formulary.

[0208] In another embodiment, the invention provides a method for choosing a drug for inclusion in the formulary. This method comprises identifying a group of drugs that are prescribed to treat or alleviate the same medical condition, symptoms or disease, and determining for each drug a haplotype profile that is correlated with an acceptable therapeutic response profile for that drug. Then, the frequency of each of these haplotype profiles in the population served by the formulary is determined. A drug is chosen for the formulary based on the determined haplotype profile frequencies. For example, the drug whose correlated haplotype profile is the most frequent of the identified haplotype profiles may be the only drug from the group included in the formulary, or alternately, each drug in the group whose haplotype profile is present above a certain percentage in the population served by the formulary may be chosen.

[0209] It should be noted that many other embodiments are within the spirit of the invention and the preceding is only by way of example, and should not be construed to limit the invention to any of the specific details disclosed above.

What is claimed is:

1. A method for recruiting a new user for a genome management service, comprising:

obtaining a cell sample from a person;

waiting a period of time;

after the period of time has elapsed, seeking from the person final permission to have his or her genomic data managed;

analyzing at least a portion of the person's genome; and

storing the resultant genomic data electronically.

2. The method of claim 1 wherein said cell sample is obtained via a cheek swab.

3. The method of claim 1 wherein said sample is obtained in a mobile unit.

4. The method of claim 1 wherein said sample is obtained in a kiosk.

5. The method of claim 1 wherein said sample is obtained in a physician's office.

6. The method of claim 1 wherein said period of time is one week.

7. The method of claim 1 wherein the resultant genomic data is stored on a data card.

8. The method of claim 7 wherein said data card is kept by the user.

9. The method of claim 7 wherein said data card is the only location where said genomic data is stored.

10. The method of claim 1 wherein the genomic data is stored on a secure server.

11. A device for maintaining an individual's genomic data, comprising:

a data storage unit in which the individual's genomic data is stored; and

a self destruct unit, which deletes said data on said device when a trigger event occurs.

12. The device of claim 11, wherein said trigger event is an attempt to copy the data stored on said device.

13. The device of claim 11, wherein said trigger event is an unauthorized attempt to read data from the device.

14. The device of claim 11, wherein said data is stored in an encrypted format.

15. The device of claim 11, wherein said data storage device is kept by the individual.

16. A data card for maintaining an individual's genomic data, comprising a data storage unit in which the individual's genomic data is stored.

17. The data card of claim 16, further comprising a self-destruct unit, which deletes said data on said device when a trigger event occurs.

18. The data card of claim 17, wherein said trigger event is an attempt to copy the data stored on said device.

19. The data card of claim 17, wherein said trigger event is an unauthorized attempt to read data from the card.

20. The data card of claim 16, wherein said data is stored in an encrypted format.

21. The data card of claim 16, wherein said data card is kept by the individual.

22. A method for providing product usage advice for an individual, comprising:

receiving the individual's genomic data;

using said genomic data to consult a database or table, the database or table correlating genomic data with responses to products; and

creating a report containing product usage advice for one or more products.

23. The method of claim 22, wherein said correlations are obtained by using a computer program.

24. The method of claim 22, wherein said receiving further includes receiving any necessary additional information.

25. The method of claim 22, wherein said using step further includes consulting the database or table using additional information.

26. The method of claim 22, wherein said database or table further correlates additional information with responses to products.

27. The method of claim 22, further including the step of updating said report when said product is purchased.

28. The method of claim 22, wherein said receiving is performed in conjunction with a point of sale operation.

29. The method of claim 28, wherein said point of sale operation is a transaction using a data card.

30. The method of claim 28, wherein said point of sale operation is a transaction using a cash register.

31. The method of claim 28, wherein said point of sale operation is an online purchase.

32. The method of claim 22, wherein said product usage advice is a prediction of the individual's response to one or more products.

33. The method of claim 22, wherein said product usage advice is a dosage recommendation for one or more products.

34. The method of claim 22, wherein said product usage advice is a prediction of side effects for one or more products.

35. The method of claim 24, wherein said additional information includes a proposed usage suggestion for one or more products.

36. The method of claim 35, wherein said product usage advice is a prediction of the individual's response to the proposed product or products.

37. The method of claim 35, wherein product usage advice is a recommendation of one or more alternative products.

38. The method of claim 22 wherein said report is provided to the individual.

39. The method of claim 22 wherein said report is provided to a healthcare provided authorized by the individual.

40. The method of claim 22 wherein said report is provided to an expert assisting the individual, but the individual's genomic data is not.

41. The method of claim 22 wherein a fee is charged for each report created.

42. The method of claim 22, wherein said database or table correlates the individual's genomic data with a response to certain drugs.

43. The method of claim 22, additionally including the steps of:

receiving feedback concerning said individual's actual response to one or more of said products; and

updating said database or table based on said feedback.

44. A method for producing marketing data, comprising:

receiving from a group of individuals their genomic data;

receiving from said group of individuals data concerning their purchasing or consumption habits;

determining correlations between said genomic data and said purchasing or consumption habits; and

making a prediction concerning an individual's purchasing or consumption habits based on that individual's genomic data.

45. The method of claim 44, wherein said correlations are stored in a database or table.

46. The method of claim 44, wherein said correlations are obtained by using a computer program.

47. The method of claim 44, wherein said correlations are statistical.

48. The method of claim 44, wherein the said correlations contain no personally-identifying data related to said individuals.

49. The method of claim 44, with the additional step of selling said correlations to interested parties.

50. The method of claim 44, wherein members of said group are paid for their participation.

51. The method of claim 44, wherein said data concerning purchasing habits is received when a data card is used to make a purchase.

52. The method of claim 44, additionally including the steps of:

receiving feedback relating to the accuracy of said prediction and/or correlations; and

updating said prediction and/or correlations based on said feedback.

53. A method for marketing products to individuals based on their genomic data, comprising:

receiving from a group of individuals their genomic data;

receiving from said group of individuals data concerning their purchasing or consumption habits;

determining correlations between said genomic data and said purchasing or consumption habits;

making a prediction concerning an individual's purchasing or consumption habits based on that individual's genomic data; and

making a product suggestion.

54. The method of claim 53, wherein said correlations are stored in a database or table.

55. The method of claim 53, wherein said correlations are obtained by using a computer program.

56. The method of claim 53, wherein said correlations are statistical.

57. The method of claim 53, wherein the said correlations contain no personally-identifying data related to said individuals.

58. The method of claim 53, with the additional step of selling said correlations to interested parties.

59. The method of claim 53, with the additional step of selling said product suggestions to interested parties.

60. The method of claim 53, with the additional step of offering said product suggestions to said individuals.

61. The method of claim 53, wherein members of said group are paid for their participation.

62. The method of claim 53, wherein said data concerning purchasing habits is received when a data card is used to make a purchase.

63. The method of claim 53, additionally including the steps of:

receiving feedback relating to the appeal of the suggested product; and

updating said suggestion and/or correlations based on said feedback.

64. A method of providing a gaming experience to an individual based on his or her genomic data, comprising:

receiving the genomic data of said individual; and

affecting gameplay using said genomic data; whereby the individual's gaming experience is due at least in part to his or her genomic data.

65. The method of claim 64, wherein said affecting involves assigning the individual to a team.

66. The method of claim 64, wherein said affecting involves the manipulation of visual gameplay aspects.

67. The method of claim 64, wherein said affecting involves the manipulation of aural gameplay aspects.

68. The method of claim 64, wherein said affecting involves giving game characters strengths or weaknesses.

69. The method of claim 64, additionally including the steps of:

receiving feedback relating to said gaming experience; and

revising said affecting based on said feedback.

70. A method of providing an individual with lifestyle advice related to his or her genomic data, comprising:

using an individual's genomic data to consult a database or table which correlates genomic data with lifestyle advice; and

receiving, as a result of said consultation, said lifestyle advice.

71. The method of claim 70 wherein said correlations are obtained using a computer program.

72. The method of claim 70 wherein said genomic data is haplotypes or haplotype pairs.

73. The method of claim 70 wherein said lifestyle advice comprises recommendations on taking preventative steps against the onset of an illness.

74. The method of claim 70 wherein said lifestyle advice comprises diet recommendations.

75. The method of claim 70 wherein said lifestyle advice comprises exercise, recommendations.

76. The method of claim 70 wherein said lifestyle advice comprises information about unique genotypical aspects of the individual.

77. The method of claim 70, additionally including the step of providing the services of a genetic counselor to explain said lifestyle information.

78. The method of claim 70, additionally including the steps of:

receiving feedback relating to the accuracy of said lifestyle advice; and

updating said database or table based on said feedback.

79. A method of providing an individual with lifestyle advice related to his or her genomic data, comprising:

using an individual's genomic data to consult a database which correlates genomic data with information related to that genomic data;

receiving, as a result of said consultation, information related to said genomic data; and

providing lifestyle advice related to said information.

80. The method of claim 79 wherein said correlations are obtained using a computer program.

81. The method of claim 79 wherein said genomic data is haplotypes or haplotype pairs.

82. The method of claim 79 wherein said lifestyle advice comprises recommendations on taking preventative steps against the onset of an illness.

83. The method of claim 79 wherein said lifestyle advice comprises diet recommendations.

84. The method of claim 79 wherein said lifestyle advice comprises exercise recommendations.

85. The method of claim 79 wherein said lifestyle advice comprises information about unique genotypical aspects of the individual.

86. The method of claim 79, additionally including the step of providing the services of a genetic counselor to explain said lifestyle information.

87. The method of claim 79, additionally including the steps of:

receiving feedback relating to the accuracy of said lifestyle advice; and

updating said advice and/or said database or table based on said feedback.

88. A method of designing products based on an individual's genomic data, comprising:

obtaining the individual's genomic data; and

creating a design for said product based on said genomic data.

89. The method of claim 88 wherein said creating involves consulting a database or table which correlates certain genomic data with certain designs.

90. The method of claim 89, additionally including the steps of:

receiving feedback relating to the appeal of said design; and

updating said database or table based on said feedback.

91. The method of claim 88 wherein said creating involves using a computer program which correlates certain genomic data with certain designs.

92. The method of claim 91, additionally including the steps of:

receiving feedback relating to the appeal of said design; and

updating said computer program based on said feedback.

93. The method of claim 88 wherein said creating involves executing a design algorithm which takes said genomic data as an input.

94. The method of claim 93, additionally including the steps of:

receiving feedback relating to the appeal of said design; and

updating said algorithm based on said feedback.

95. The method of claim 88 wherein said product is a food.

96. The method of claim 88 wherein said product is artwork.

97. The method of claim 88 wherein said product is wearing apparel.

98. The method of claim 88 wherein said product is a perfume.

99. The method of claim 88 wherein said product is jewelry.

100. The method of claim 88 wherein said product is music.

101. A method for marketing an individual's genomic data, comprising:

contacting a party interested in using an individual's genomic data;

negotiating with the party to determine the terms of use for said data;

seeking the individual's consent to allow said party to use said data under the determined terms of use; and

if consent is received, providing, under the determined terms of use, said genomic data to said party.

102. The method of claim 101 wherein said providing is performed in such a manner that the party is not allowed to permanently keep said genomic data.

103. The method of claim 101 wherein said negotiations involves determining a price that said party will pay said individual for use of said genomic data.

104. The method of claim 101 wherein said negotiations involves determining the portions of the individual's genomic data that will be used by the party.

105. A method for providing an individual with low price genomic-based services, comprising:

receiving from the individual a request for a genomic-based service;

negotiating with a plurality of parties capable of providing said service in order to determine which party of said parties is willing to offer said service at a lower price than the remainder of said parties; and

upon receiving the individual's consent, allowing said party which offered said lower price to perform said service.

106. The method of claim 105 wherein said service is performing a medical test based on said individual's genomic data.

107. The method of claim 105 wherein said service is providing information based on said individual's genomic data.

108. The method of claim 105 wherein said service is providing artwork whose design is based on said individual's genomic data.

109. The method of claim 105, including the additional step of charging the individual a fee.

110. The method of claim 105, including the additional step of charging said service provider a fee.

111. The method of claim 105, wherein said negotiating step includes considering the quality of the providers.

112. The method of claim 111, wherein said receiving step further includes receiving from the individual quality requirements.

113. The method of claim 111, wherein the management company sets quality requirements.

114. A billing method for a genomic data managing service, comprising:

charging a management fee; and

charging a fee for each access of said data.

115. The method of claim 114, wherein said management fee is a periodic fee for maintaining said data.

116. The method of claim 115 wherein said periodic fee is a fee charged each time a predetermined interval elapses.

117. The method of claim 114, wherein said management fee is a fee for setting up a new account.

118. The method of claim 114, wherein said management fee is a fee for adding or deleting genomic data.

119. The method of claim 114, wherein said management fee is a fee for adding or deleting non-genomic data.

120. A method for providing an individual's genomic data to a party, comprising:

receiving from a party a request for an individual's genomic data;

negotiating with the party to determine the terms of use for said data;

seeking the individual's consent to allow said party to use said data under the determined terms of use; and

if consent is received, providing, under the determined terms of use, said genomic data to said party.

121. The method of claim 120 wherein said providing is performed in such a manner that the party is not allowed to hold or posses said genomic data.

122. The method of claim 120 wherein said negotiating involves determining a price that said party will pay said individual for use of said genomic data.

123. The method of claim 120 wherein said negotiating involves determining which portions of the individual's genomic data will be used by the party.

124. A method for securely transmitting an individual's genomic data to a party, comprising:

storing an individual's genomic data on a data card; and

physically transporting said data card to said party.

125. The method of claim 124, wherein said data card deletes the data it carries when a trigger event occurs.

126. The method of claim 125 wherein said trigger event is an attempt to read the data on the card using an incorrect decryption key.

127. The method of claim 125 wherein said trigger event is an attempt to use the data for a purpose other than the one agreed upon.

128. The method of claim 125 wherein said trigger event is the expiration of a count-down timer.

129. The method of claim 125 wherein said trigger event is said party failing to acknowledge receipt of said data.

130. The method of claim 124 wherein said data is stored in an encrypted manner.

131. A method for securely transmitting an individual's genomic data to a party, comprising:

creating a data package, said data package containing the individual's genomic data; and

allowing said party to download said package over a network.

132. The method of claim 131 wherein said package deletes the data it carries when a trigger event occurs.

133. The method of claim 132 wherein said trigger event is an attempt to read the data in the package using an incorrect decryption key.

134. The method of claim 132 wherein said trigger event is an attempt to use the data for a purpose other than the one agreed upon.

135. The method of claim 132 wherein said trigger event is the expiration of a count-down timer.

136. The method of claim 132 wherein said trigger event is said party failing to acknowledge receipt of said data.

137. The method of claim 131 wherein said package contains said data in an encrypted format.

138. The method of claim 131, wherein the party is selected from the group consisting of the individual, the individual's physician, the individual's genetic counselor, the individual's hospital, the individual's physician's office, the individual's pharmacy and the individual's pharmacist.

139. A system for providing product usage advice for an individual, comprising:

a memory having program code stored therein;

a database or table correlating genomic data with responses to products; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

receiving the individual's genomic data;

using said genomic data to consult the database or table; and

creating a report containing product usage advice for one or more products.

140. The system of claim 139 wherein said correlations are obtained by using a computer program.

141. The system of claim 139, wherein said receiving further includes receiving any necessary additional information.

142. The system of claim 139, wherein said using step further includes consulting the database or table using additional information.

143. The system of claim 139, wherein said database or table further correlates additional information with responses to products.

144. The system of claim 139, further including the step of updating said report when said product is purchased.

145. The system of claim 139, wherein said receiving is performed in conjunction with a point of sale operation.

146. The system of claim 145, wherein said point of sale operation is a transaction using a data card.

147. The system of claim 145, wherein said point of sale operation is a transaction using a cash register.

148. The system of claim 145, wherein said point of sale operation is an online purchase.

149. The system of claim 139, wherein said product usage advice is a prediction of the individual's response to one or more products.

150. The system of claim 139, wherein said product usage advice is a dosage recommendation for one or more products.

151. The system of claim 139, wherein said product usage advice is a prediction of side effects for one or more products.

152. The system of claim 141, wherein said additional information includes a proposed usage suggestion for one or more products.

153. The system of claim 152, wherein said product usage advice is a prediction of the individual's response to the proposed product or products.

154. The system of claim 152, wherein product usage advice is a recommendation of one or more alternative products.

155. The system of claim 139 wherein said report is provided to the individual.

156. The system of claim 139 wherein said report is provided to an expert assisting the individual, but the individual's genomic data is not.

157. The system of claim 139 wherein a fee is charged for each report created.

158. The system of claim 139, wherein said database or table correlates haplotypes or haplotype pairs with a response to certain drugs.

159. The system of claim 139, additionally including the steps of:

receiving feedback concerning said individual's actual response to one or more of said products; and

updating said database or table based on said feedback.

160. A system for producing marketing data, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

receiving from a group of individuals their genomic data;

receiving from said group of individuals data concerning their purchasing habits;

determining correlations between said genomic data and said purchasing habits; and

making a prediction concerning an individual's purchasing habits based on that individual's genomic data.

161. The system of claim 160 wherein said correlations are stored in a database or table.

162. The system of claim 160 wherein said correlations are obtained by using a computer program.

163. The system of claim 160, wherein said correlations are statistical.

164. The system of claim 160, wherein the said correlations contain no personally-identifying data related to said individuals.

165. The system of claim 160, with the additional step of selling said correlations to interested parties.

166. The system of claim 160, wherein members of said group are paid for their participation.

167. The system of claim 160, wherein said data concerning purchasing habits is received when a data card is used to make a purchase.

168. The system of claim 160, additionally including the steps of:

receiving feedback relating to the accuracy of said prediction and/or correlations; and

updating said prediction and/or correlations based on said feedback.

169. A system for marketing products to individuals based on their genomic data, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

receiving from a group of individuals their genomic data;

receiving from said group of individuals data concerning their purchasing habits;

determining correlations between said genomic data and said purchasing habits;

making a prediction concerning an individual's purchasing habits based on that individual's genomic data; and

making a product suggestion.

170. The system of claim 169 wherein said correlations are stored in a database or table.

171. The system of claim 169 wherein said correlations are obtained by using a computer program.

172. The system of claim 169, wherein said correlations are statistical.

173. The system of claim 169, wherein the said correlations contain no personally-identifying data related to said individuals.

174. The system of claim 169, with the additional step of selling said correlations to interested parties.

175. The system of claim 169, with the additional step of selling said product suggestions to interested parties.

176. The system of claim 169, with the additional step of offering said product suggestions to said individuals.

177. The system of claim 169, wherein members of said group are paid for their participation.

178. The system of claim 169, wherein said data concerning purchasing habits is received when a data card is used to make a purchase.

179. The system of claim 169, additionally including the steps of:

receiving feedback relating to the appeal of the suggested product; and

updating said suggestion and/or correlations based on said feedback.

180. A system for providing a gaming experience to an individual based on his or her genomic data, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

receiving the genomic data of said individual; and

affecting gameplay using said genomic data; whereby the individual's gaming experience is due at least in part to his or her genomic data.

181. The system of claim 180, wherein said affecting involves assigning the individual to a team.

182. The system of claim 180, wherein said affecting involves the manipulation of visual gameplay aspects.

183. The system of claim 180, wherein said affecting involves the manipulation of aural gameplay aspects.

184. The system of claim 180, wherein said affecting involves giving game characters strengths or weaknesses.

185. The system of claim 180, additionally including the steps of:

receiving feedback relating to said gaming experience; and

revising said affecting based on said feedback.

186. A system for providing an individual with lifestyle advice related to his or her genomic data, comprising:

a memory having program code stored therein;

a database or table correlating genomic data with lifestyle advice; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

using the individual's genomic data to consult the database or table; and

receiving, as a result of said consultation, said lifestyle advice.

187. The system of claim 186, wherein said correlations are obtained using a computer program.

188. The system of claim 186, wherein said genomic data is haplotypes or haplotype pairs.

189. The system of claim 186, wherein said lifestyle advice comprises recommendations on taking preventative steps against the onset of an illness.

190. The system of claim 186, wherein said lifestyle advice comprises diet recommendations.

191. The system of claim 186, wherein said lifestyle advice comprises exercise recommendations.

192. The system of claim 186, wherein said lifestyle advice comprises information about unique genotypical aspects of the individual.

193. The system of claim 186, additionally including the step of providing the services of a genetic counselor to explain said lifestyle information.

194. The system of claim 186, additionally including the steps of:

receiving feedback relating to the accuracy of said lifestyle advice; and

updating said database or table based on said feedback.

195. A system for providing an individual with lifestyle advice related to his or her genomic data, comprising:

a memory having program code stored therein;

a database or table which correlates genomic data with information related to that genomic data; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

using the individual's genomic data to consult the database or table;

receiving, as a result of said consultation, information related to said genomic data; and

providing lifestyle advice related to said information.

196. The system of claim 195, wherein said correlations are obtained using a computer program

197. The system of claim 195, wherein said genomic data is haplotypes or haplotype pairs.

198. The system of claim 195, wherein said lifestyle advice comprises recommendations on taking preventative steps against the onset of an illness.

199. The system of claim 195, wherein said lifestyle advice comprises diet recommendations.

200. The system of claim 195, wherein said lifestyle advice comprises exercise recommendations.

201. The system of claim 195, wherein said lifestyle advice comprises information about unique genotypical aspects of the individual.

202. The system of claim 195, additionally including the step of providing the services of a genetic counselor to explain said lifestyle information.

203. The system of claim 195, additionally including the steps of:

receiving feedback relating to the accuracy of said lifestyle advice; and

updating said advice and/or said database or table based on said feedback.

204. A system for designing products based on an individual's genomic data, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

obtaining the individual's genomic data; and

creating a design for said product based on said genomic data.

205. The system of claim 204, wherein said creating involves consulting a database or table which correlates certain genomic data with certain designs.

206. The system of claim 205, additionally including the steps of:

receiving feedback relating to the appeal of said design; and

updating said database or table based on said feedback.

207. The system of claim 204, wherein said creating involves using a computer program which correlates certain genomic data with certain designs.

208. The system of claim 207, additionally including the steps of:

receiving feedback relating to the appeal of said design; and

updating said computer program based on said feedback.

209. The system of claim 204, wherein said creating involves executing a design algorithm which takes said genomic data as an input.

210. The system of claim 209, additionally including the steps of:

receiving feedback relating to the appeal of said design; and

updating said algorithm based on said feedback.

211. The system of claim 204, wherein said product is a food.

212. The system of claim 204, wherein said product is artwork.

213. The system of claim 204, wherein said product is wearing apparel.

214. The system of claim 204, wherein said product is a perfume.

215. The system of claim 204, wherein said product is jewelry.

216. The system of claim 204, wherein said product is music.

217. A system for marketing an individual's genomic data, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

contacting a party interested in using an individual's genomic data;

negotiating with the party to determine the terms of use for said data;

seeking the individual's consent to allow said party to use said data under the determined terms of use; and

if consent is received, providing, under the determined terms of use, said genomic data to said party.

218. The system of claim 217 wherein said providing is performed in such a manner that the party is not allowed to permanently keep said genomic data.

219. The system of claim 217 wherein said negotiations involves determining a price that said party will pay said individual for use of said genomic data.

220. The system of claim 217 wherein said negotiations involves determining the portions of the individual's genomic data that will be used by the party.

221. A system for providing an individual with low price genomic-based services, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

receiving from the individual a request for a genomic-based service;

negotiating with a plurality of parties capable of providing said service in order to determine which party of said parties is willing to offer said service at a lower price than the remainder of said parties; and

upon receiving the individual's consent, allowing said party which offered said lower price to perform said service.

222. The system of claim 221 wherein said service is performing a medical test based on said individual's genomic data.

223. The system of claim 221 wherein said service is providing information based on said individual's genomic data.

224. The system of claim 221 wherein said service is providing artwork whose design is based on said individual's genomic data.

225. The system of claim 221, including the additional step of charging the individual a fee.

226. The system of claim 221, including the additional step of charging said service provider a fee.

227. The system of claim 221, wherein said negotiating step includes considering the quality of the providers.

228. The system of claim 227, wherein said receiving step further includes receiving from the individual quality requirements.

229. The system of claim 227, wherein the management company sets quality requirements.

230. A billing system for a genomic data managing service, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

charging a management fee; and

charging a fee for each access of said data.

231. The system of claim 230, wherein said management fee is a periodic fee for maintaining said data.

232. The system of claim 231, wherein said periodic fee is a fee charged each time a predetermined interval elapses.

233. The system of claim 230, wherein said management fee is a fee for setting up a new account.

234. The system of claim 230, wherein said management fee is a fee for adding or deleting genomic data.

235. The system of claim 230, wherein said management fee is a fee for adding or deleting non-genomic data.

236. A system for providing an individual's genomic data to a party, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code;

wherein said program code, when executed by said processor, causes said processor to perform the steps of:

receiving from a party a request for an individual's genomic data;

negotiating with the party to determine the terms of use for said data;

seeking the individual's consent to allow said party to use said data under the determined terms of use; and

if consent is received, providing, under the determined terms of use, said genomic data to said party.

237. The system of claim 236, wherein said providing is performed in such a manner that the party is not allowed to hold or posses said genomic data.

238. The system of claim 236, wherein said negotiating involves determining a price that said party will pay said individual for 108 of said genomic data.

239. The system of claim 236, wherein said negotiating involves determining which portions of the individual's genomic data will be used by the party.

240. A system for securely transmitting an individual's genomic data to a party, comprising:

a memory having program code stored therein;

a data card interface; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

storing an individual's genomic data on a data card; and

arranging for the physical transport of said data card to said party.

241. The system of claim 240, wherein said data card deletes the data it carries when a trigger event occurs.

242. The system of claim 241, wherein said trigger event is an attempt to read the data on the card using an incorrect decryption key.

243. The system of claim 241, wherein said trigger event is an attempt to use the data for a purpose other than the one agreed upon.

244. The system of claim 241, wherein said trigger event is the expiration of a count-down timer.

245. The system of claim 241, wherein said trigger event is said party failing to acknowledge receipt of said data.

246. The system of claim 241, wherein said data is stored in an encrypted manner.

247. A system for securely transmitting an individual's genomic data to a party, comprising:

a memory having program code stored therein; and

a processor connected to said memory for carrying out instructions in accordance with said stored program code; wherein said program code, when executed by said processor, causes said processor to perform the steps of:

creating a data package, said data package containing the individual's genomic data; and

allowing said party to download said package over a network.

248. The system of claim 247, wherein said package deletes the data it carries when a trigger event occurs.

249. The system of claim 248, wherein said trigger event is an attempt to read the data in the package using an incorrect decryption key.

250. The system of claim 248, wherein said trigger event is an attempt to use the data for a purpose other than the one agreed upon.

251. The system of claim 248, wherein said trigger event is the expiration of a count-down timer.

252. The system of claim 248, wherein said trigger event is said party failing to acknowledge receipt of said data.

253. The system of claim 247, wherein said package contains said data in an encrypted format.

254. A method for reimbursing a physician for the care of a patient comprising the steps of:

determining whether the physician prescribed a drug that the management company recommended for the patient based on the patient's therapeutic needs and the patient's genomic data; and

reimbursing the physician if the physician prescribed a recommended drug to the patient.

255. A method of marketing a product in a geographic region of interest, comprising:

obtaining information relating to correlations between users' response to the product and a haplotype profile;

determining the frequency of the haplotype profile in the population living in the geographic region; and

making a marketing decision for the geographic region based on the determined frequency of the haplotype profile.

256. The method of claim 255, wherein the product is a drug or biologic.

257. The method of claim 256, wherein the marketing decision is to proceed with marketing the product if the determined frequency of the haplotype profile is at least 25%.

258. The method of claim 256, wherein the marketing decision is to proceed with marketing the product if the determined frequency of the haplotype profile is at least 50%.

259. The method of claim 256, wherein the geographic region is a state or territory of the United States of America.

260. The method of claim 256, wherein the geographic region is a country.

261. A method for developing a new product to satisfy a particular unmet demand or need of a population, comprising:

identifying a haplotype profile that is correlated with the unmet demand or need in the population;

determining a functional cause for the correlation between the haplotype profile and the unmet need or demand; and

developing a new product designed to avoid the functional cause.

262. The method of claim 261, wherein the unmet demand or need is weight management.

263. The method of claim 261, wherein the unmet demand or need is addiction to smoking.

264. The method of claim 261, wherein the unmet demand or need is addiction to alcohol.

265. The method of claim 261, wherein the unmet demand or need is a treatment for schizophrenia.

266. The method of claim 261, wherein the unmet demand or need is a treatment for dyslipidemia.

267. The method of claim 261, wherein the unmet demand or need is a treatment for diabetes.

268. A method for marketing a drug for inclusion in a formulary, comprising:

identifying a haplotype profile that is correlated with a good therapeutic profile for the drug;

determining the frequency of the haplotype profile in the population served by the formulary; and

making a marketing decision based on the determined frequency of the haplotype profile.

269. The method of claim 168, wherein the marketing decision is to pursue inclusion in the formulary if the determined frequency of the haplotype profile is at least 25%.

270. A method for choosing a drug for inclusion in a formulary, comprising:

identifying a group of drugs that are prescribed to treat or alleviate the same medical condition, symptoms or disease;

obtaining for each drug a haplotype profile that is correlated with an acceptable therapeutic response profile for that drug; and

determining in the population served by the formulary the frequency of each obtained haplotype profile; and

chosing a drug for the formulary based on the determined haplotype profile frequencies.

271. The method of claim 271, wherein the chosing step comprises selecting the drug whose correlated haplotype profile has the highest frequency.

272. The method of claim 271, wherein the chosing step comprises selecting each drug whose correlated haplotype profile has a frequency greater than 25%.

* * * * *

XII. RELATED PROCEEDINGS APPENDIX

None.

XIII. UNPUBLISHED AUTHORITY APPENDIX

A. ***In re Beasley***

B. **Federal Circuit Rule Suspension**

In re Beasley

LEXSEE 2004 U.S. APP. LEXIS 25055

IN RE BRUCE BEASLEY

04-1225

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

117 Fed. Appx. 739; 2004 U.S. App. LEXIS 25055

December 7, 2004, Decided

NOTICE: [**1] THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO THE RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS FOR RULES GOVERNING CITATION TO UNPUBLISHED OR NONPRECEDENTIAL OPINIONS OR ORDERS.

PRIOR HISTORY: (Serial No. 07/636,839).

DISPOSITION: Vacated and remanded.

CASE SUMMARY:

PROCEDURAL POSTURE: A patent applicant sought a patent directed to the generation of images or markings on a video display screen using a light pen, but a patent examiner determined that the claimed invention was obvious from prior art. The applicant appealed the decision of the Board of Patent Appeals and Interferences which upheld the examiner's determination.

OVERVIEW: The applicant contended that a feature of mapping the display screen into the memory on a point-by-point basis was not disclosed by prior art, but the examiner found that a skilled artisan would have been motivated to make such a combination to read out rapidly the bit map format. The court held that the finding of obviousness as a matter of law was not supported by citation to relevant portions of prior art. Both the examiner and the Board, relying on their status as skilled artisans, provided only conclusory statements of generalized advantages and convenient assumptions about skilled artisans. Such statements and assumptions were inadequate to support the finding of motivation in the obviousness analysis which could not be resolved on subjective belief and unknown authority.

OUTCOME: The decision upholding the rejection of the patent application was vacated, and the matter was remanded for further proceedings.

LexisNexis(R) Headnotes

Patent Law > Nonobviousness > Elements & Tests > Claimed Invention as a Whole
Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard
Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues
[HN1] A claimed invention may be found to be obvious if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *35 U.S.C.S. § 103(a)*. Whether an invention is obvious under *§ 103* is a question of law based on underlying findings of fact.

Civil Procedure > Appeals > Standards of Review > De Novo Review
Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview

[HN2] a court reviews a legal conclusion of obviousness by the Board of Patent Appeals and Interferences de novo, and its underlying factual determinations for substantial evidence. Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
[HN3] For a prima facie case of obviousness to exist, there must be some objective teaching in the prior art or knowledge generally available to one of ordinary skill in the art that would lead that individual to combine the relevant teachings of the references. The motivation, suggestion, or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases, the nature of the problem to be solved.

Patent Law > Jurisdiction & Review > Standards of Review > Substantial Evidence
Patent Law > Nonobviousness > Elements & Tests > Prior Art
[HN4] For purposes of obviousness, the presence or absence of a motivation to combine references is a question of fact which is evaluated under the substantial evidence standard.

Patent Law > Nonobviousness > Elements & Tests > Hindsight
Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN5] Given the subtle but powerful attraction of a hindsight-based obviousness analysis, courts require a rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. This is consonant with the obligation of the Board of Patent Appeals and Interferences to develop an evidentiary basis for its factual findings to allow for judicial review under the substantial evidence standard that is both deferential and meaningful.

Administrative Law > Judicial Review > Reviewability > Factual Determinations
Criminal Law & Procedure > Appeals > Standards of Review > Substantial Evidence
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN6] For purposes of obviousness, in evaluating a finding of motivation by the Board of Patent Appeals and Interferences, the court looks to the record for all of the relevant information upon which the Board relied in rendering its decision. That record, when before the court, is closed, in that the Board's decision must be justified within the four corners of that record.

Patent Law > Inequitable Conduct > General Overview
Patent Law > Nonobviousness > Evidence & Procedure > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN7] Generalized claims of what the secondary references teach and of what a skilled artisan would have been well aware fail to satisfy the level of specificity that is required for an obviousness analysis. Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
[HN8] The rationale supporting an obviousness rejection may be based on common knowledge in the art or well-known prior art. The examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being well-known in the art.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
[HN9] See *37 CFR 1.104(d)(2)*.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
[HN10] For purposes of obviousness, assertions of technical facts in areas of esoteric technology must always be supported by citation of some reference work and allegations concerning specific knowledge of the prior art, which might be peculiar to a particular art, should also be supported. Manual Pat. Examining P. § 2144.03.

Evidence > Judicial Notice > Domestic Laws
Patent Law > U.S. Patent & Trademark Office Proceedings > Examinations > General Overview
[HN11] The Manual of Patent Examining Procedure (MPEP) is commonly relied upon by patent examiners on procedural matters. While the MPEP does not have

the force of law, it is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN12] Conclusory statements of generalized advantages and convenient assumptions about skilled artisans are inadequate to support a finding of motivation in an obviousness analysis, which is a factual question that cannot be resolved on subjective belief and unknown authority. Under such circumstances, with respect to core factual findings, the Board of Patent Appeals and Interferences must point to some concrete evidence in the record in support of them, rather than relying on its assessment of what is well recognized or of what a skilled artisan would be well aware. To hold otherwise would render the process of appellate review for substantial evidence on the record a meaningless exercise.

Administrative Law > Judicial Review > Standards of Review > General Overview
[HN13] Courts may not accept appellate counsel's post hoc rationalization for agency action.

Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN14] A court's review must be limited to those grounds relied on and articulated by the Board of Patent Appeals and Interferences; otherwise, the applicant may be deprived of a fair opportunity to support his position.

Administrative Law > Judicial Review > Standards of Review > General Overview
[HN15] A court is powerless to affirm administrative action by substituting what it considers to be a more adequate or proper basis.

JUDGES: Before LOURIE, Circuit Judge, ARCHER, Senior Circuit Judge, and DYK, Circuit Judge. Opinion for the court filed by Circuit Judge LOURIE. Dissenting opinion filed by Circuit Judge DYK.

OPINION BY: LOURIE

OPINION

[*739] LOURIE, *Circuit Judge.*

Bruce Beasley appeals from the decision of the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences affirming the rejection of claims 1-6 of U.S. Patent Application 07/636,839 as obvious under *35 U.S.C. § 103. Ex parte Beasley, 2002 Pat. App. LEXIS 329, Appeal No. 2001-2202, Paper No. 38 (B. P.A.I. Aug. 29, 2002)* ("*Decision on Appeal*"); *Ex parte Beasley*, Appeal No. 2001-2202, Paper No. 40 (B. P.A.I. Oct. 27, 2003) ("*Decision on Request for Rehearing*"). Because the Board's key factual findings relating to its obviousness analysis are not supported by substantial evidence, the Board erred in concluding that the claims would have been obvious [**2] as a matter of law. We accordingly *vacate and remand.*

[*740] BACKGROUND

On January 2, 1991, Beasley filed U.S. Patent Application 07/636,839 directed to the generation of images or markings on a video display screen using a light pen, so as to point to or otherwise indicate information of interest. Representative claim 1 recites:

> 1. In a system for forming an image on a display screen scanned in frames by a beam:
>
> a light pen movable relative to the screen and having a light sensing element for providing a signal when the position of the light pen coincides with the position of the beam,
>
> a memory having a plurality of addressable storage locations, means for *mapping the display screen into the memory on a point-by-point basis* by sequentially addressing the memory locations in synchronization with the position of the beam *to provide a one-to-one correspondence* between the memory locations and the points on the screen,
>
> means responsive to the signal from the light pen for writing data into the memory at locations corresponding to the position of the light pen on the screen during successive frames,
>
> means for reading the data out of the memory locations as they are addressed, [**3] and
>
> means responsive to the data read out of the memory for producing an image corresponding to the points where the light pen is positioned during successive frames.

(emphases and paragraphing added).

Previously, the '839 application had been the subject of an appeal to this court, which affirmed the rejection of claims 1-6 under *35 U.S.C. §§ 102* and *103* in view of *U.S. Patent 3,832,485* ("Pieters"). *In re Beasley, 1999 U.S. App. LEXIS 16695, No. 99-1055, 1999 WL 515480 (Fed. Cir. July 20, 1999)* (nonprecedential) ("*Beasley* I"). [1] Beasley thereafter filed a Continued Prosecution Application, in which he amended independent claims 1 and 4 to specifically include the feature of "mapping the display screen into the memory on a point-by-point basis ... to provide a one-to-one correspondence" between the memory locations and the points on the screen (hereinafter referred to as the "point-by-point mapping limitation"). [2]

1 In *Beasley I*, claims 1, 3, 4, and 6 had been rejected as being anticipated by Pieters, and claims 2 and 5 had been rejected as being obvious in view of the same. *Beasley I, 1999 U.S. App. LEXIS 16695, 1999 WL 515480 at **1*. Pieters is directed to an apparatus for creating delineations on images using, *inter alia*, a light pen. Pieters, abstract.

[**4]

2 In the prior appeal, Beasley argued that the point-by-point mapping limitation was to be read into independent claims 1 and 4, in an attempt to avoid anticipation by Pieters. The court in *Beasley I* concluded that the language of the claims was not sufficiently narrow to require this limitation to be read therein, and consequently affirmed the anticipation rejection. *Beasley I, 1999 U.S. App. LEXIS 16695, 1999 WL 515480 at **3*. After amending the claims to expressly recite the point-by-point mapping limitation, Beasley is now before us again. Although the point-by-point mapping limitation is cast in means-plus-function form, *see 35 U.S.C. § 112, P6 (2000)*, the parties do not dispute whether any of the cited references discloses an equivalent structure. Accordingly, we need not identify or consider the structures in Beasley's application that correspond to that function.

Observing that Pieters, by itself, did not disclose the point-by-point mapping limitation, the examiner rejected the amended claims for obviousness under *§ 103* in view of Pieters combined with either one [**5] of *U.S. Patent 3,973,245* ("Belser") or *U.S. Patent 4,847,604* ("Doyle"). [3] The examiner cited [*741] Belser and Doyle as each disclosing "a conventional bit map memory mapping a display screen into the memory on a point by point basis," and that "it would have been obvious to one of ordinary skill in the art to substitute Belser's [or Doyle's] bit map memory" for the content addressable memory ("CAM") used in Pieters. Jan. 7, 2000 Office Action at 2-3. A skilled artisan would have been motivated to make such a combination, alleged the examiner, "because image data stored in the bit map format can be read out rapidly." *Id.*

3 Belser concerns a method and apparatus for "converting information in coded form into a dot matrix or raster form," Belser, col. 2, ll. 22-24, and presents in considerable detail an algorithm for reformatting data. Belser, col. 5, l. 23 through col. 9, l. 20. Doyle is directed to a system that allows a user to point to a feature on an image and cause descriptive information (*e.g.*, text or a magnified view) to appear. Doyle, col. 11, l. 13 through col. 12, l. 18.

[**6] Beasley responded that the examiner had failed to establish a *prima facie* case of obviousness because replacing the CAM in Pieters with the memories in Belser and Doyle would require "a complete restructuring" of the system shown in Pieters, which was "not within the purview of obviousness." Apr. 6, 2000 Resp. to Office Action at 2. Arguing that the cited references failed to provide any motivation for the combination, Beasley stressed that the examiner's suggestion for the substitution "appeared to be based entirely on applicant's own disclosure" in an attempt to "piece together" the prior art so as to render the claimed invention obvious. *Id.* Beasley criticized the rationale proffered by the examiner--that "data stored in a bit map format can be read out rapidly"--as "falling far short of the necessary motivation for the combination." *Id.*

The examiner rejected Beasley's arguments in a final office action, by repeating the substance of the Jan. 7, 2000 Office Action, and by further alleging that it was "well known in [the] computer display art to substitute a bit map memory for a conventional memory such as the memory used by Pieters." Jun. 14, 2000 Office Action [**7] at 4. Insisting that the "advantage of using ... bit map memory over ... conventional memory [was] well recognized," the examiner listed three advantages: (1) increasing the display rate; (2) ensuring proper correlation of image locations with display locations; and (3) minimizing data processing and storage requirements. *Id.* In view of those "well recognized" advantages, reasoned the examiner, "it would have been obvious to one of ordinary skill" to make the substitution. *Id.* at 5.

Beasley appealed the final rejection to the Board, reiterating his arguments against obviousness. The Board agreed with the examiner's reasoning and affirmed [4] the rejection of claims 1-6. [5] *Decision on Appeal at 8*. The Board found that the cited references suggested to skilled

artisans "that if more rapid readout of image data is desired, the bit map memory, rather than the CAM of Pieters, should be employed." *Id. at 5-6.* With respect to Beasley's restructuring argument, the Board stated that "the artisan skilled in the image display and memory arts would [*742] have been well aware of the restructuring" involved when making the substitution. *Id. at 6.* Disagreeing with Beasley that the [**8] examiner's proposed substitution of one memory type for another was "unsupported," the Board reasoned that the "artisan would clearly have understood, from the applied references, the different types of memories available (CAM versus bit map), and their comparative advantages, and would have chosen implementation of one over the other for the advantages sought." *Id.* Concluding that the examiner established a *prima facie* case of obviousness, the Board sustained the rejection of claims 1-6.

> 4 To the extent the Board adopted the examiner's position as its own, we shall refer to the examiner's findings and conclusions as those of the Board. *See In re Paulsen, 30 F.3d 1475, 1478 n.6 (Fed. Cir. 1994).*
>
> 5 Our discussion will focus on independent claim 1, and, in particular, the point-by-point mapping limitation. The only other independent claim is claim 4, which is directed to a method, but is otherwise similar to independent claim 1 in all material respects. Since Beasley has not made separate patentability arguments for claim 4, or for any of the dependent claims, those claims will stand or fall together with claim 1. *See In re Kaslow, 707 F.2d 1366, 1376 (Fed. Cir. 1983).*

[**9] Beasley filed a request for reconsideration, which the Board denied. *Decision on Request for Rehearing* at 5. Beasley timely appealed the Board's decision to this court, and we have jurisdiction pursuant to *28 U.S.C. § 1295(a)(4)(A).*

DISCUSSION

[HN1] A claimed invention may be found to have been obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *35 U.S.C. § 103(a) (2000).* Whether an invention would have been obvious under *§ 103* is a question of law based on underlying findings of fact. *In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000).* [HN2] We review the Board's legal conclusion of obviousness *de novo*, and its underlying factual determinations for substantial evidence. *In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000).* Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id. at 1312* (quoting [**10] *Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938)).*

On appeal, Beasley urges reversal on the basis that the record does not support the Board's determination that the examiner established a *prima facie* case of obviousness. [HN3] For a *prima facie* case of obviousness to exist, there must be "some objective teaching in the prior art or ... knowledge generally available to one of ordinary skill in the art [that] would lead that individual to combine the relevant teachings of the references." *In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).* "The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved." *Kotzab, 217 F.3d at 1370.*

[HN4] The presence or absence of a motivation to combine references is a question of fact, *In re Dembiczak, 175 F.3d 994, 1000 (Fed. Cir. 1999),* which is evaluated under the substantial evidence standard. *Gartside, 203 F.3d at 1316.* Beasley contends that we have before us a case of impermissible hindsight reconstruction, [**11] in which the examiner's finding of a motivation to substitute the memory used in either Belser or Doyle for the CAM in Pieters rests on generalized statements of advantages without regard to the desirability or the feasibility of modifying Pieters. [HN5] Given the "subtle but powerful attraction of a hindsight-based obviousness analysis," we require a "rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *Dembiczak, 175 F.3d at 999.* This is consonant with the obligation of the Board to develop an evidentiary basis for its factual findings to allow for judicial review under the substantial evidence standard that is both deferential and [*743] meaningful. *See In re Lee, 277 F.3d 1338, 1344 (Fed. Cir. 2002).*

[HN6] In evaluating the Board's finding of motivation, we look to the record, for "all of the relevant information upon which the Board relied in rendering its decision." *Gartside, 203 F.3d at 1314.* "That record, when before us, is closed, in that the Board's decision must be justified within the four corners of that record." *Id.* For the purposes of the present appeal, the record indicates [**12] that there have been no less than five occasions, since the filing of the Continued Prosecution Application with the amended claims, on which the Board and the examiner have had the opportunity to develop a factual record that establishes substantial evidence of a motivation to combine Pieters with either Belser or Doyle. They failed to do so in each instance. Our review of (1) the Jan. 7, 2000 Office Action; (2) the Jun. 14, 2000 Office Action; (3) the Feb. 13, 2001 Examiner's Answer; (4) the

Decision on Appeal; and (5) the *Decision on Request for Rehearing* reveals that the assertions pertaining to the advantages of one type of memory over another that had been advanced by the examiner and the Board for the express purpose of showing motivation for the proposed substitution have been set forth without any supporting citations to relevant portions of either Pieters, Belser, Doyle, or any other authority.

For example, the examiner's allegation in the Jan. 7, 2000 Office Action that "image data stored in the bit map format can be read out rapidly" has been repeated axiomatically throughout the record in justifying the replacement of the CAM in Pieters. Neither the Board nor [**13] the examiner has identified in the record any source of information--either from the references cited or otherwise--from which they base their comparison of the relative speed advantages of "bit map memories" over CAMs. Similarly, the assertion in the Jun. 14, 2000 Office Action that the "advantage of using ... bit map memory over ... conventional memory is well recognized" appears unaccompanied by any indication of its origins. [6]

> 6 While the abstract of Doyle was cited for the proposition that the use of "bit map memory" ensures proper correlation of image locations with display locations, and minimizes data processing and storage requirements, a closer inspection of Doyle reveals that these "advantages" arise out of a specific arrangement for encoding image information, rather than from any intrinsic characteristic of "bit map memories" in general. Doyle, col. 4, ll. 15-19 ("The advantages ... stem from encoding information about a video image as a pixel bit map and a color map in which the addresses or indices of the color map are correlated with the addresses or pointers to strings of descriptive information about predefined features of the video image.").

[**14] In adopting the examiner's position, the Board made no effort to substantiate the examiner's assertions by invoking any identifiable authority. Instead, the Board relied on the examiner's and its own knowledge as skilled artisans. For example, the Board claimed that "the secondary references" suggested to skilled artisans "that if more rapid readout of image data is desired, the bit map memory, rather than the CAM of Pieters, should be employed." *Decision on Appeal at 5-6*. Similarly, in dismissing Beasley's restructuring argument, the Board alleged that a skilled artisan would have been "well aware" of the restructuring involved. *Id. at 6*. Under the MPEP provisions [7] in effect [*744] at the time, such [HN7] generalized claims of what "the secondary references" teach and of what the skilled artisan would have been "well aware" fail to satisfy the level of specificity that is required. *Cf. Kotzab, 217 F.3d at 1371* ("Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed."). The MPEP provides guidelines for relying on official notice and [**15] personal knowledge, which the examiner did not follow in this case:

> [HN8] The rationale supporting an obviousness rejection may be based on common knowledge in the art or "well-known" prior art. The examiner may take official notice of facts outside of the record which are capable of *instant and unquestionable demonstration* as being "well-known" in the art. *In re Ahlert, 57 C.C.P.A. 1023, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970)* ...
>
> ...
>
> [HN9] When a rejection is based on facts within the personal knowledge of the examiner, *the data should be stated as specifically as possible*, and the facts must be supported, when called for by the applicant, by an affidavit from the examiner. Such an affidavit is subject to contradiction or explanation by the affidavits of the applicant and other persons. See *37 CFR 1.104(d)(2)*.
>
> ...
>
> For further views on official notice, see *In re Ahlert, 57 C.C.P.A. 1023, 424 F.2d 1088, 1091, 165 USPQ 418, 420-421 (CCPA 1970)* ("[HN10] *Assertions of technical facts in areas of esoteric technology must always be supported by citation of some reference work*" and "allegations concerning specific 'knowledge' [**16] of the prior art, which might be peculiar to a particular art should also be supported." ...

MPEP § 2144.03 (7th ed. 1998) (emphases added); *see also* MPEP § 2144.03 (7th ed., rev. 1, 2000). Certainly, the relative speed advantages of CAMs vis-a-vis "bitmap memories" and the feasibility of substituting one for the other can hardly be described as a fact that is of "instant and unquestionable demonstration" for the purpose of taking official notice unsupported by any citation.

7 [HN11] The Manual of Patent Examining Procedure ("MPEP") is commonly relied upon by patent examiners on procedural matters. *Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1439 (Fed. Cir. 1984)*. "While the MPEP does not have the force of law, it is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith." *Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n. 10 (Fed. Cir. 1995)*.

The record reflects that the examiner and the [**17] Board have managed to find motivation for substituting one type of memory for another without providing a citation of any relevant, identifiable source of information justifying such substitution. The statements made by the Examiner, upon which the Board relied, amount to no more than conclusory statements of generalized advantages and convenient assumptions about skilled artisans. At least under the MPEP then in effect, such [HN12] statements and assumptions are inadequate to support a finding of motivation, which is a factual question that cannot be resolved on "subjective belief and unknown authority." *Lee, 277 F.3d at 1344*. Under such circumstances, with respect to core factual findings, "the Board must point to some concrete evidence in the record in support" of them, rather than relying on its assessment of what is "well recognized" or what a skilled artisan would be "well aware." *In re Zurko, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001)*. "To hold otherwise would render the process of appellate review for substantial evidence on the record a meaningless exercise." *Id. at 1386* (citing *Baltimore & Ohio R.R. Co. v. Aberdeen & Rockfish R.R. Co., 393 U.S. 87, 91-92, 21 L. Ed. 2d 219, 89 S. Ct. 280 (1968)*). [**18]

The PTO, perhaps realizing the deficiencies in the record in this regard, provides numerous citations in its brief to specific [*745] passages in Pieters, Belser, and Doyle in a valiant attempt to muster substantiation for the Board's findings. We cannot consider such *post hoc* attempts at bolstering the record in our review for substantial evidence. *Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168, 9 L. Ed. 2d 207, 83 S. Ct. 239 (1962)* [HN13] ("Courts may not accept appellate counsel's *post hoc* rationalization for agency action."). [HN14] Our review must be limited to those grounds relied on and articulated by the Board; otherwise, the applicant may be deprived of a fair opportunity to support his position. *See Lee, 277 F.3d at 1345*; *see also SEC v. Chenery Corp., 332 U.S. 194, 196, 91 L. Ed. 1995, 67 S. Ct. 1575 (1947)* [HN15] ("The court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis.").

CONCLUSION

For the above reasons, we conclude that the Board's determination that Beasley's claimed invention would have been obvious in view of the combination of Pieters with either Belser or Doyle is not [**19] supported by substantial evidence. Accordingly, we vacate the Board's decision and remand for further proceedings not inconsistent with this opinion.

DISSENT BY: DYK

DISSENT

DYK, *Circuit Judge*, dissenting.

I respectfully dissent. Under our decision in *Lee* the Board may not rely on common knowledge and common sense in rejecting a claim as obvious. *In re Lee, 277 F.3d 1338, 1344-45 (Fed. Cir. 2002)*. But both the examiner and the Board are presumed to be skilled in the art, *id. at 1345*, as the majority recognizes, *ante* at 8. They may properly rely on that knowledge in making rejections for obviousness, but "when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record." *Lee, 277 F.3d at 1345*.

That is exactly what the examiner and Board have done here. The patent examiner rejected Beasley's claims as obvious over Pieters in view of either Besler or Doyle, finding a motivation to combine in the fact that "image data stored in the bit map format can be read out rapidly." Jan. 7, 2000 Office Action at 2. The examiner sustained his rejection in the subsequent [**20] Office Action and specifically addressed Beasley's argument that there was no motivation to combine. The examiner noted that "the advantage of using the bit map memory over the conventional memory is well recognized" and listed three advantages: (1) increasing the display rate; (2) ensuring proper correlation of image locations with display locations; and (3) minimizing data processing and storage requirements. June 14, 2000 Office Action at 4. The Board agreed with the reasoning of the examiner and further found that an "artisan skilled in the image display and memory arts would have been well aware of the restructuring and manners of address which would need to be changed in order to substitute one type of memory for another." *Ex parte Beasley, 2002 Pat. App. LEXIS 329, Appeal No. 2001-2202, Paper No. 38, at 6 (B. P.A.I. Aug. 29, 2002)*. I see no error in the Board's reliance on the PTO's own specialized knowledge. The effect is merely to create a prima facie case, and to shift the burden to the patent applicant. Here the applicant did not refute the factual findings of the Board and the patent examiner, but merely offered lawyer argument to contradict the Board's findings. Under these circumstances the [**21] application was properly rejected.

With this said, I agree that the MPEP provision in effect at the time is not a model of clarity and can be read as recognizing [*746] only a very limited scope for the use of the PTO's expertise. MPEP § 2144.03 (7th ed. 1998). However, the current version appears to allow greater latitude. MPEP § 2144.03 (8th ed., rev. 2, 2004). In future cases, where the PTO has provided us with an interpretation of the new MPEP provisions, we will need to address the extent to which the new version of the MPEP gives the PTO greater scope to rely on its own expert knowledge.

Federal Circuit Rule Suspension

United States Court of Appeals for the Federal Circuit

Rules & Forms

The Federal Circuit Rules of Practice, 2006 edition, are available for download.

Notice:Attached are revised Court of Appeals Miscellaneous Fee Schedule effective January 1, 2007, revised Federal Circuit Rule 47.3, effective September 1, 2006, and new Federal Circuit Rule 32.1, effective December 1, 2006. Both should be inserted into the RULES OF PRACTICE dated May 1, 2006. Federal Circuit Rule 47.6 is superseded effective December 1, 2006.

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Form 10	Statement Concerning Discrimination
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